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

Selection Criteria:

Product Name:				
Product Active Ingredient:				
Active Ingredient:	[HYDROXYCHLOROQUINE,HYDROXYCHLOROQUINE DIPHOSPHATE,HYDROXYCHLOROQUINE SULFATE]			
Active Moiety:				
FDA Received Date:	From:	01-Dec-2019	To:	15-Apr-2020
MedDRA® Version* :	22.1			
Total Cases**:	5490			
Number of Pages:	3954			

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

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

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

U.S. FOOD & DRUG ADMINISTRATION

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Dec-2019	16848284	NON-EXPEDITED			CA-AMGEN-CANSP2019156482		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Condition Aggravated; Insomnia; Musculoskeletal Pain; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Oral	15 Milligram, Weekly (2.5 Mg Tabs (Tablets), 6 Tabs)		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, 2x/Day (Enteric Coated Tablet)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15924086	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007486			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Pain; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15929029	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007665		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15929086	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007652			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15930665	EXPEDITED (15-DAY)		DS, HO	CA-TEVA-2019-CA-1007381		57 YR	Female	CAN

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

Blood Creatine Phosphokinase Increased; Condition Aggravated; Drug Ineffective; Haematemesis; Hepatotoxicity; Joint Swelling; Nausea; Platelet Count Increased; Vitamin D Decreased; Vomiting	Methotrexate	S	Oral		Barr
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral	20 Milligram Daily;	Not Reported
	Hydroxychloroquine /00072603/	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Betahistine	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Rosuvastatin	C	Unknown		Not Reported
	Vitamin C	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15930794	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007502		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Milligram Daily;		Not Reported
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Prednisone		C	Unknown	Not Reported
	Tramadol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15930804	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007766		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15936139	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007503			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15936148	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010048			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15939918	EXPEDITED (15-DAY)		CA, HO, OT	CA-TEVA-2019-CA-1008093			Female	CAN

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

Abdominal Pain Upper; Anaemia Of Chronic Disease; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Haemodilution; Headache; Hepatic Cyst; Hepatic Haematoma; Interferon Gamma Release Assay Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Musculoskeletal Stiffness; Neutropenia; Pulmonary Fibrosis; Pulmonary Mass; Pyrexia; Renal Cyst; Thalassaemia	Methotrexate	S	Subcutaneous		Barr
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral	20 Milligram Daily;	Not Reported
	Celebrex	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Remicade	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Isoniazid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15942075	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007294		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

				otherwise specified)			
	Prednisone		C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15942208	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007582		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Naprosyn			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15945502	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010899		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Naproxen Sodium			C	Unknown			Not Reported

Folic Acid	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Ramipril	C	Unknown	2.5 Milligram Daily;		Not Reported
Tylenol	C	Unknown	1300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	15998611	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1017443		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased; Sleep Disorder Due To A General Medical Condition	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported
	Otezla			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Co-Syntex			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Stelara	S	Unknown		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	16904610	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201803-000961			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebral Vasoconstriction; Headache; Interleukin Level Increased; Neuropsychiatric Lupus; Pericardial Effusion; Pyrexia; Reversible Cerebral Vasoconstriction Syndrome; Tremor; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Endoxan			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Neoral			C		Unk		Not Reported
	Neoral			C		Increased Dose		Not Reported
	Prednisolone			C		Unk		Not Reported
	Prednisolone			C		Increased Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	16947693	NON-EXPEDITED			US-PFIZER INC-2019456482		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	8 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	6 Mg, Weekly		Pfizer
	Prednisone			S		Unk		Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Plaquenil			S		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17096243	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5778			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17096244	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5779			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Mobility Decreased; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097256	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1144225		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Methotrexate			S	Unknown			Barr

Administered; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Leflunomide		S	Unknown		Barr
	Enbrel		S	Unknown		Not Reported
	Etanercept		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Rituximab		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097258	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143916		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097261	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144383			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity; Pulmonary Toxicity	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097271	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144506		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	200 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	11.2 Milligram Daily;		Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sodium Aurothiomalate			S	Parenteral	1 Gram Daily;		Not Reported

Sulfasalazine	S	Unknown	1 Gram Daily;		Not Reported
Lyrica	C	Unknown			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
Xeljanz	C	Oral			Not Reported
Prednisone	C	Unknown	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097316	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144419		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097328	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144381			Female	CAN

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

Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Methotrexate		S	Unknown		Barr
	Actemra		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil		S	Unknown	400 Milligram Daily;	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Celebrex		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097329	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143910			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Haemorrhage	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine Besilate			C		2.5 Milligram Daily;		Not Reported
	Gabapentin			C		400 Milligram Daily;		Not Reported
	Prednisone			C	Intravenous (not otherwise specified)	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097333	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145351		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster;	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported

Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram Daily;	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Restasis	C	Unknown		Not Reported
	Prednisone	C		10 Milligram Daily;	Not Reported
	Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097339	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144262		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C				Not Reported

	Prevacid	C	Not Reported
	Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097354	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144386		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097355	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144259		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097372	EXPEDITED (15-DAY)		OT	CA-ROCHE-2481383		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097689	EXPEDITED (15-DAY)		OT	NVSC2019US051742		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysarthria; Facial Paralysis	Gsk2118436			S	Oral	150 Mg, Bid		Novartis
	Gsk1120212			S	Oral	2 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate Tablets Usp			S	Oral	600 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17097955	EXPEDITED (15-DAY)		OT	NVSC2019GB053585		16 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Product Use In Unapproved Indication; Pulmonary Alveolar	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Prednisolone			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	250 Mg (Three Times		Not Reported

Haemorrhage

Weekly)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17098068	EXPEDITED (15-DAY)		CA	GB-PFIZER INC-2019510857		1 DAY	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Palate; Maternal Exposure During Pregnancy	Sulfasalazine			S	Transplacental	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Transplacental	200 Mg, Daily		Not Reported
	Folic Acid			C	Transplacental	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17098354	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019512755		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscular Weakness; Myalgia; Peripheral Sensorimotor Neuropathy	Atorvastatin Calcium			S	Oral	40 Mg, 1x/Day		Pfizer
	Doxycycline			S	Oral	200 Mg, 1x/Day		Not Reported
	Metronidazole			S	Oral	1500 Mg, 1x/Day		Not Reported
	Tavanic			S	Oral	500 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Lansoprazole			C	Oral	15 Mg, 1x/Day		Not Reported
	Clopidogrel			C	Oral	75 Mg, 1x/Day		Not Reported
	Fluconazole			C	Oral	200 Mg, 1x/Day		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17099182	EXPEDITED (15-DAY)		HO	NVSC2019FR049563		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertrophic	Cosentyx			S	Subcutaneous	150 Mg, Qmo		Novartis

Cardiomyopathy; Ventricular Arrhythmia	Plaquenil	S	Oral	2 Df, Qd		Not Reported
	Levothyrox	C	Oral	1 Df, Qd		Not Reported
	Renitec	C	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17100227	EXPEDITED (15-DAY)		HO	CA-ROCHE-2481058		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Malaise; Throat Cancer; Thrombosis	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17100374	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1115977		88 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Bisoprolol			S	Oral	2.5 Milligram, Qd		Not Reported
	Doxycycline			S	Oral	200 Milligram, Qd		Not Reported
	Flagyl /00012501/			S	Oral	1500 Milligram, Qd		Mylan
	Plaquenil /00072602/			S	Oral	600 Milligram, Qd		Mylan
	Lovenox			S	Subcutaneous	0.4 Milliliter, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17100967	NON-EXPEDITED			US-BAYER-2019-206506		41 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Drug Hypersensitivity; Lip Swelling; Nausea; Pruritus; Vision Blurred	Cipro			S		Unk		Bayer
	Bactrim			S		Unk		Not Reported
	Keflex [Cefalexin]			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Relafen			S		Unk		Not Reported
	Topamax			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17100995	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144426		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Fatigue; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Treatment Failure	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Neoral	S	Oral		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101001	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144417		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Joint Arthroplasty; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;		Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Plaquenil	S	Unknown			Not Reported
Rituximab	S	Unknown			Not Reported
Rituximab	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Tocilizumab	S	Unknown			Not Reported
Leflunomide	C	Unknown	20 Milligram Daily;		Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101002	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144394			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Intolerance; Interstitial Lung Disease; Pulmonary Mass; Sinusitis; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101005	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144437			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia;	Methotrexate			S	Unknown			Barr

Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Off Label Use; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Leflunomide	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Bifidobacterium Bifidum	C	Unknown		Not Reported
	Loperamide	C	Oral		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101007	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144443			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101402	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143891		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101409	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143911			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C	Subcutaneous			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101410	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144083		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Pulmonary Fibrosis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101579	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144421			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101591	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144442		60 YR	Female	CAN

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

Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Leflunomide	S	Unknown	20 Milligram Daily;	Barr
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown	4000 Mol Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	C			Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101595	EXPEDITED (15-DAY)		DS	FR-MYLANLABS-2019M1117199		26 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ejection Fraction Decreased; Hypertrophic Cardiomyopathy	Prednisone			S	Oral	8 Milligram, Qd		Not Reported
	Imurel /00001501/			S	Oral	2 Milligram/Kilogram, Qd		Mylan
	Lyrica			S	Oral	Unk		Mylan
	Plaquenil /00072602/			S	Oral	Unk		Mylan
	Endoxan /00021102/			S	Intravenous (not otherwise specified)	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17101919	EXPEDITED (15-DAY)		DE, HO	GR-BAUSCH-BL-2019-063444		57 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Brain Oedema; Condition Aggravated; Confusional State; Encephalitis Japanese B; Meningitis Bacterial; Product Use In Unapproved Indication; Speech Disorder; Treatment Failure	Prednisolone			S	Unknown			Bausch And Lomb
	Prednisolone			S				Bausch And Lomb
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17102033	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI-FK201913271		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
West Nile Viral Infection	Methylprednisolone (Manufacturer Unknown)			S	Unknown	High-Dose		Fresenius Medical Care
	Methotrexate (Manufacturer Unknown)			S	Unknown	Unknown		Fresenius Medical Care
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfamethoxazole/Trimethoprim			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17102285	EXPEDITED (15-DAY)		OT	CA-MAYNE PHARMA-2019MYN000843			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Dyspnoea; Rash	Erythromycin			S	Unknown	Unk		Mayne
	Cephalexin /00145501/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported

Arava	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Simponi	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17102516	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144355			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17102520	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143961		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17102521	EXPEDITED (15-DAY)		DS, HO	CA-TEVA-2019-CA-1144351		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported

	Folic Acid	C	Unknown	Not Reported
	Levothyroxine Sodium	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2019	17102532	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144357			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15567436	NON-EXPEDITED			US-PFIZER INC-2018432992		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15939608	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1008100		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lower Respiratory Tract Infection; Treatment Failure	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15939789	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1008090			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Other			Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15942237	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010011		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15949861	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010757			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Discomfort; Joint Stiffness; Respiratory Tract Infection; Rheumatoid Arthritis; Sinusitis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Hydroxychloroquine Sulfate	S	Oral	Not Reported
Celebrex	C	Unknown	Not Reported
L-Thyroxine	C	Unknown	Not Reported
Nexium	C	Unknown	Not Reported
Tylenol Arthritis Pain 8hour	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15952040	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010726		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Methotrexate			S	Subcutaneous			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15954621	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010985			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15957503	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1012795			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Keratitis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15963930	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010775			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sarilumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown	1300 Milligram Daily;		Not Reported
	Acetaminophen			C		1300 Milligram Daily;		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aluminum Acetate\Benzethonium Chloride Atacand			C	Unknown			Not Reported

Ergocalciferol	C	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Hydrodiuril	C	Unknown			Not Reported
Neurontin	C	Unknown	1800 Milligram Daily;		Not Reported
Premarin	C	Unknown			Not Reported
Tylenol	C	Unknown	1300 Milligram Daily;		Not Reported
Aluminium Acetate	C	Unknown			Not Reported
Benzethonium Chloride	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15983876	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1015158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Seizure; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15993644	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1015603		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Mass; Mass Excision; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15993951	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1015570		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown	400 Milligram Daily;		Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15998585	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016696		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Vomiting	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	15998600	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016844		63 YR	Female	CAN

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

Angioedema; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Loss Of Personal Independence In Daily Activities; Pneumonia; Pruritus; Pulmonary Fibrosis; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Barr
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Imuran	S	Unknown		Not Reported
	Methyl Salicylate	S	Unknown		Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	16073266	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1021604			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/ 00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	16565754	NON-EXPEDITED			US-PFIZER INC-2019298276		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer
	Cefpodoxime Proxetil			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Amoxicillin Sodium And Potassium Clavulanate			S		Unk		Not Reported
	Erythromycin Base			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Amitriptylline			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Oxycodone			S		Unk		Not Reported
	Oxycodone And Acetaminophen			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	16866076	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1113892			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Impaired Work Ability; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label	Ibuprofen			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Naprosyn			S	Unknown			Not Reported

Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Folic Acid		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Oral	200 Milligram Daily;	Not Reported
	Prednisone		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	16996290	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019476158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Joint Range Of Motion Decreased; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Unknown	1 Every 2 Weeks		Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Enbrel			S	Unknown			Pfizer
	Infliximab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported
	Remicade			S	Unknown			Not Reported
	Acidophilus			C	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Deflazacort			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported

Ergocalciferol	C	Unknown			Not Reported
Hydromorphone Hydrochloride	C	Unknown			Not Reported
Januvia	C	Unknown			Not Reported
Kenalog [Triamcinolone Acetonide]	C	Unknown			Not Reported
Lidocaine	C	Topical			Not Reported
Metronidazole	C	Unknown	Unk		Not Reported
Nitroglycerin	C	Unknown			Not Reported
Pantoloc [Pantoprazole]	C	Unknown			Not Reported
Pregabalin	C	Unknown			Not Reported
Risedronate	C	Unknown			Not Reported
Rosuvastatin Calcium	C	Unknown			Not Reported
Salbutamol	C	Unknown			Not Reported
Triamcinolone	C	Unknown			Not Reported
Tylenol [Paracetamol]	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17101401	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144348		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported
	Arava	C			Not Reported
	Lyrica	C			Not Reported
	Prednisone	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17102538	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144510			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rash; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17103648	EXPEDITED (15-DAY)		HO	CA-ROCHE-2481388		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer; Thrombosis	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Tacrolimus	S	Oral		Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17104636	NON-EXPEDITED			US-UCBSA-2017051005			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Intolerance	Cimzia			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Tofacitinib			C	Oral	1 Mg, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17104656	NON-EXPEDITED			US-UCBSA-2018003810		71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Butterfly Rash; Drug Ineffective; Gastrointestinal Disorder; Mental Status Changes; Pruritus	Cimzia			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17104894	EXPEDITED (15-DAY)		OT	CA-ROCHE-2481093		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported

Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17104914	EXPEDITED (15-DAY)		CA, DS, OT	NVSC2019FR050452			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondrodystrophy; Chondropathy; Dysmorphism; Low Birth Weight Baby; Maternal Exposure During Pregnancy	Trileptal			S	Transplacental	Unk		Novartis
	Paracetamol			S	Transplacental	Unk		Not Reported
	Keppra			S	Transplacental	Unk		Not Reported
	Plaquenil			S	Transplacental	Unk		Not Reported
	Actonel			C	Transplacental	Unk		Not Reported
	Speciafoldine			C	Transplacental	Unk		Not Reported
	Kaleorid			C	Transplacental	Unk		Not Reported
	Orocal D3			C	Unknown	Unk		Not Reported
	Diffu-K			C	Transplacental	Unk		Not Reported
	Cortancyl			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17104937	EXPEDITED (15-DAY)		OT	CA-ROCHE-2482153			Male	CAN

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

Drug Ineffective; Drug Intolerance; Dyspnoea; Hypertension; Neoplasm Malignant	Rituximab		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Leflunomide		S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105083	EXPEDITED (15-DAY)		HO	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-19-058		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspergillus Infection; Haemophagocytic Lymphohistiocytosis; Multiple Organ Dysfunction Syndrome; Pseudomonas Infection	Prednisone			S	Unknown			Westward
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105146	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1144448			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tofacitinib	S	Unknown	10 Milligram Daily;	Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105151	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144250			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105283	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1143920		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105318	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144409			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Synovitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Amlodipine	C	Oral	5 Milligram Daily;	Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105382	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144290		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea; Stress	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			C				Not Reported
	Prednisone			C	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Oral	6 Milligram Daily;		Not Reported
	Mefenamic Acid			C	Unknown			Not Reported
	Mefenamic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105397	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144410		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Ineffective; Drug Intolerance; Dyspepsia; Dyspepsia; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105411	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145570		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug	Methotrexate			S	Subcutaneous			Barr
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

Intolerance; Nausea; Off Label Use	Enbrel		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;	Not Reported
	Naprosyn		S	Unknown	1000 Milligram Daily;	Not Reported
	Orencia		S	Subcutaneous		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown	1000 Milligram Daily;	Not Reported
	Sulfasalazine		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105418	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144282			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105547	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1144279		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported

	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown	1000 Milligram Daily;	Not Reported
	Desoximetasone		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105570	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1143964		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105666	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1144286		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash;	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr

Urticaria	Leflunomide	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Atenolol	C	Oral	50 Milligram Daily;		Not Reported
	Hydrochlorothiazide	C	Oral	25 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2481399			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105916	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019521803		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Infliximab			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Etanercept			S	Unknown			Pfizer
	Actemra			S	Intravenous (not otherwise specified)	624 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Naproxen			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Acetaminophen			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Oxyneo			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported
	Lasix [Furosemide]			C				Not Reported
	Methylprednisolone			C				Not Reported
	Naprosyn [Naproxen]			C				Not Reported
	Oxycontin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17105973	EXPEDITED (15-DAY)		OT	CA-ROCHE-2403354			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17107120	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144642		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Plaquenil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17107204	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144703			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Drug Ineffective; Mouth Ulceration; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17107205	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145583		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	2.8571 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C	Endocervical	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17107868	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144961			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Nausea; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Naprosyn /00256201/			C	Unknown			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Tylenol Arthritis Pain 8h			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17107899	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144969		63 YR	Female	CAN

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

Breast Cancer; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Methotrexate	S	Unknown	Barr
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17107903	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144962		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Off Label Use; Prescribed Overdose; Rheumatoid Arthritis; Synovitis; Vomiting	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Sulfasalazine	S	Unknown	1000 Milligram Daily;		Not Reported
Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
Celebrex	C	Unknown			Not Reported
Celebrex	C	Unknown			Not Reported
Naprosyn /00256201/	C	Unknown	1000 Milligram Daily;		Not Reported
Naprosyn /00256201/	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17107906	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145512			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Contraindicated Product Administered; Drug Ineffective; Joint Injury; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Pain; Urticaria	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Pertussis Vaccine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17107908	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145414			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Methotrexate			S	Unknown			Barr

Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Dec-2019	17108802	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-063176			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Diclofenac Sodium			S	Unknown	Not Specified		Not Reported
	Desoximetasone			S	Oral	Not Specified		Not Reported
	Actemra			S	Unknown	Not Specified		Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	Not Specified		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial	Not Specified		Not Reported

Orencia	S	Intravenous (not otherwise specified)			Not Reported
Orencia	S	Subcutaneous			Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Plaquenil	S	Unknown			Not Reported
Prednisone	S	Unknown	Not Specified		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Xeljan	S	Unknown			Not Reported
Cortisone Acetate	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	9010565	EXPEDITED (15-DAY)		HO, OT	DK-SANOFI-AVENTIS-2013SA001345		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; C-Reactive Protein Increased; Fatigue; Joint Swelling; Off Label Use; Weight Decreased	Hydroxychloroquine			S	Unknown	250 Mg,Qd		Sanofi
	Prednisolone			S	Unknown	20 Mg,Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg,Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	13894400	EXPEDITED (15-DAY)		OT	CA-ROCHE-1980860		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Rheumatoid Arthritis; Synovitis	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 320 Days		Not Reported

	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown	Therapy Duration: 171 Days	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Meloxicam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15598164	NON-EXPEDITED			US-PFIZER INC-2018447319		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer
	Etanercept			S		Unk		Pfizer
	Depo-Medrol			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15743077	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-990533		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Sciatica; Sinusitis; Therapeutic Product Effect	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Incomplete; Treatment Failure	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15866035	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1003135		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Therapeutic Response Decreased; Thyroid Neoplasm	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15917142	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007217		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15932517	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1008051			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naprosyn			S	Oral	1000 Milligram Daily;		Not Reported
	Naprosyn			S				Not Reported

Orencia	S	Unknown			Not Reported
Rituximab	S	Unknown			Not Reported
Vioxx	S	Unknown			Not Reported
Leflunomide	C	Unknown			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15949858	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010881			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fatigue; Joint Effusion; Pain; Polyarthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Lyrica			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15951929	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1011460		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Drug Ineffective; Hip Fracture; Intervertebral Disc Disorder; Nausea; Rheumatoid Arthritis; Stress Fracture; Vomiting	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15954579	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1011476		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Oral			Barr
	Methotrexate			S	Parenteral			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15954603	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1010142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)			
	Remicade	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;		Not Reported
	Xeljanz	S	Unknown	25 Milligram Daily;		Not Reported
	Arava	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15959671	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1012950			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15959677	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1012969		70 YR	Female	CAN

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

Drug Ineffective; Eye Disorder; Fatigue	Methotrexate	S	Subcutaneous	Barr
	Actemra	S	Unknown	Not Reported
	Apo-Acetaminophen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Dilaudid	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15965246	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014276			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15969555	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010787			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	15992817	EXPEDITED (15-DAY)		CA, OT	CA-TEVA-2019-CA-1015846			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia;	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Anakinra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

Rheumatoid Arthritis	Arava	S	Oral	10 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Naprosyn	S	Oral	1000 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Vioxx	S	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	16134028	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019136528			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Celecoxib			S		200 Mg, 1x/Day		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Unk		Pfizer
	Sertraline Hcl			S		25 Mg, Unk		Pfizer
	Citalopram			S		20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Indomethacin [Indometacin]			S		50 Mg, 3x/Day		Not Reported
	Indomethacin [Indometacin]			S				Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Temazepam			S		Unk		Not Reported
	Toradol			S	Intramuscular	10 Mg, Unk		Not Reported
	Toradol			S				Not Reported
	Zopiclone			S		7.5 Mg, Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Lidocaine			C		Unk		Not Reported
	Methylprednisolone Acetate			C		80 Mg, Unk		Not Reported
	Naproxen			C		500 Mg, 2x/Day		Not Reported

	Prednisone	C	Unk	Not Reported
	Vitamin D [Colecalciferol]	C	50000 Iu, Weekly	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	16476438	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-19K-163-2831359-00		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Atrial Fibrillation; Coeliac Disease; Diarrhoea; Food Allergy; Gait Disturbance; Immobile; Injection Site Rash; Injection Site Urticaria; Peripheral Swelling; Rash; Spinal Osteoarthritis; Swelling; Urticaria	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	16826822	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1109544			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise;	Leflunomide			S	Unknown			Barr
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection; White Blood Cell Count Decreased	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	16984941	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1129084		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	16993855	EXPEDITED (15-DAY)		DS, OT	FR-ADVANZ PHARMA-201910001445			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Impaired Driving Ability; Loss Of Personal Independence In Daily Activities; Maculopathy	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Dosage Form, Bid,(1-0-1) 2,Tablets In The Morning (Film Coated Tablet)		Concordia
	Prednisone			C		1 Mg		Not Reported
	Tramadol			C		200 Mg		Not Reported
	Levothyrox			C		Unk		Not Reported
	Alprazolam			C		50 Mg		Not Reported
	Laroxyl			C	Unknown	40 Milligram Per Millilitre		Not Reported
	Furosemide			C		40 Mg		Not Reported
	Propanolol			C		160 Mg		Not Reported
	Esomeprazole			C		40 Mg		Not Reported
	Rocgel			C		Unk		Not Reported
	Psyllium Husks			C		3.6 G		Not Reported
	Spasfon			C		Unk		Not Reported
	Hydrocortisone Roussel			C		Unk Unk, Qd		Not Reported
	Hydrocortisone Roussel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	16995999	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1131115		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-	Doxycycline Hyclate			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr

Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Leflunomide	S	Unknown	10 Milligram Daily;	Barr
	Leflunomide	S	Unknown	10 Milligram Daily;	Barr
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Aurothiomalate Sodium	S	Unknown		Not Reported
	Aurothiomalate Sodium	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Rituxan	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Simponi	C	Subcutaneous		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Rituximab;Urelumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17003952	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5222			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Joint Range Of Motion Decreased; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Product Use Issue; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Acidophilus			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Deflazacort			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Hydromorphone Hydrochloride			C	Unknown			Not Reported
	Januvia			C	Unknown			Not Reported
	Kenalog			C	Unknown			Not Reported
	Lidocaine			C	Topical			Not Reported
	Metronidazole			C	Unknown			Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Pantoloc			C	Unknown			Not Reported
	Pregabalin			C	Unknown			Not Reported
	Risedronate			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported

Salbutamol	C	Unknown	Not Reported
Triamcinolone	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17107357	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201807-002265			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Exposure During Pregnancy; Glaucoma	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd, Once Daily		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Prednisolone			S	Oral	8 Mg, Freq: Unk X 1 Days		Not Reported
	Colchicine			C		Unk		Not Reported
	Heparin Calcium			C		Unk		Not Reported
	Miya Bm			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17108708	EXPEDITED (15-DAY)		OT	CA-ROCHE-2481141			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17108882	EXPEDITED (15-DAY)		OT	CA-ROCHE-2481074		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109034	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1145459			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For	Prednisolon			S	Transplacental	5 [Mg/D (Bis 4)]/ Initially 5 Mg/D Until Gw 6+2, Then		Actavis

Dates Baby					Discontinued. From Gw 23+3 Until Delivery 4 M	
	Quensyl		S	Transplacental	200 [Mg/D]	Not Reported
	Folsäure		C	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109097	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144713		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109098	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1144948			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Injury; Muscular Weakness; Nausea; Off Label Use;	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported

Treatment Failure; Vomiting	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109100	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145405			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109105	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-113430		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cystitis; Dyspnoea;	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Musculoskeletal Disorder; Pain In Extremity; Pneumonia	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109110	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145062		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Pain; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	500 Milligram Daily;		Not Reported
	Arava			C	Oral	20 Milligram Daily;		Not Reported
	Risedronate			C	Oral			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109123	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145566			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling;	Methotrexate			S	Subcutaneous	15 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported

Leukopenia; Rash; Visual Impairment	Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	1 Gram Daily;	Not Reported
	Xeljanz	C	Oral	5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109124	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145408			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109125	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145464		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Methotrexate			S	Oral			Barr

Contraindicated Product Administered; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate	S	Intramuscular		Barr
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Oral		Not Reported
	Asa	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Lantus	C	Subcutaneous	Solution Subcutaneous	Not Reported
	Lozide /00340101/	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Naprosyn /00256201/	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Ramipril	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109126	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145588			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	3 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109129	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144820			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Unknown			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109133	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145406			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109135	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145193		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109136	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145179			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Mirtazapine			S	Unknown			Teva
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109139	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145418		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Ciclosporin			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Neoral	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109140	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145519		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Off Label Use; Spinal Column Injury; Surgical Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Mobicox		C	Unknown	15 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109168	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144915		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Crohn'S Disease; Drug Ineffective; Drug Intolerance; Mobility Decreased; Nausea; Red Blood Cell Sedimentation Rate Increased; Retinitis; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; Visual Impairment	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sufate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109169	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144913		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Rituximab		S	Unknown	Not Reported
	Simponi		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109181	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145069		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109184	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144956			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia;	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Rheumatoid Arthritis	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109190	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144805		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109192	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144907			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Synovitis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109208	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145585			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109236	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1145189			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109237	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145043		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported

Incomplete; Therapy Non-Responder; Treatment Failure	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Oral	Not Reported
	Remicade		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109273	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17109373	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-113458			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Erythematosus	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17110218	EXPEDITED (15-DAY)		OT	CA-ROCHE-2483730		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17111246	EXPEDITED (15-DAY)		OT	CA-ROCHE-2483719		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17111666	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019523826			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Sulfasalazine			S	Unknown			Pfizer

	Enbrel	S	Unknown	Pfizer
	Cimzia	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Otezla	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Arava	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112210	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144993		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112214	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145733		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112215	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144719		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use	Methotrexate			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

Plaquenil	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Arava	C	Unknown			Not Reported
Codeine Phosphate	C	Unknown			Not Reported
Lyrica	C	Oral			Not Reported
Tylenol/00020001/	C	Unknown			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112240	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145845		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C		100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112247	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Hypersensitivity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Celebrex	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112369	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145538		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea; Stress	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Advil /00044201/	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Tylenol /00020001/	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112373	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144706		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Swelling; Synovitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112381	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145007		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased;	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Rheumatoid Arthritis; Sleep Disorder	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112382	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144708			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112386	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145297			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Uveitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr

Methotrexate	S	Oral		Barr
Apo-Leflunomide	S	Unknown		Not Reported
Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
Enbrel	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112389	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144811		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dermatitis Acneiform; Drug Hypersensitivity; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Hypersensitivity; Joint Swelling; Leukaemia; Nausea; Pruritus; Synovitis; Unevaluable Event	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			C		10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112390	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144835			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112392	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144815			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea; Off Label Use	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112584	EXPEDITED (15-DAY)		OT	NVSC2019AU055143			Male	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Graft Versus Host Disease In Skin	Cyclosporine			S	Unknown	100 Mg, Bid		Novartis
	Prednisolone			S	Unknown	10 Mg, Qd (Upto 75 Mg Daily)		Not Reported
	Mabthera			S	Unknown	375 Mg/M2 (4 Doses)		Not Reported
	Ibrutinib			S	Unknown	300 Mg, Qd		Not Reported
	Sirolimus			S	Unknown	2 Mg, Qd		Not Reported
	Hidroxicloroquina			S	Unknown	200 Mg, Qd		Not Reported
	Quetiapine			C	Unknown	25 Mg, Qd		Not Reported
	Lamotrigine			C	Unknown	200 Mg, Bid		Not Reported
	Valaciclovir			C	Unknown	500 Mg, Bid		Not Reported
	Bactrim Ds			C	Unknown	1 Df 3 Times Per Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112711	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144652			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)		
	Rituximab	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112712	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145024			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112794	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145633			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Oral	600 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Oral	20 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	5 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Simponi			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112795	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144937		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Dexamethasone			C	Unknown	5 Milligram Daily;		Not Reported

	Leflunomide	C	Unknown		Not Reported
	Prednisone Acetate	C	Unknown	5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112796	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145618		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown	200 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			C	Oral	10 Milligram Daily;		Not Reported
	Naproxen			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown	3 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112814	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145025		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Orencia	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Cyclobenzaprine	C	Unknown		Not Reported
	Desoximetasone	C	Unknown	5 Milligram Daily;	Not Reported
	Leflunomide	C	Unknown		Not Reported
	Prednisoloneacetate	C	Unknown	5 Milligram Daily;	Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;	Not Reported
	Tylenol/00020001/	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112836	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112869	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145202			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	2.8571 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112880	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145850		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112881	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1145553		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Synovitis; Thrombocytopenia; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			C	Subcutaneous			Not Reported
	Advil /00044201/			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown	200 Milligram Daily;		Not Reported
	Ketorolac			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112884	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145046			Male	CAN

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

Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Methotrexate	S	Oral		Barr
	Methotrexate	S	Subcutaneous		Barr
	Anakinra	S	Unknown		Not Reported
	Arava	S	Oral	10 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine /00072603/	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Naprosyn	S	Oral	500 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Vioxx	S	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112886	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144909			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112887	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145082		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Hypertension; Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Pain; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112888	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145779		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112889	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144872			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Oral	25 Milligram Daily;		Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported

	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112892	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145458			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	1000 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112895	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1145019			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomadesis; Onychomycosis	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine /00072603/	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112896	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145031			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine /00072603/	S	Unknown		Not Reported
	Naprosyn	S	Oral	1000 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Vioxx	S	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112900	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145021		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram Daily;		Not Reported

Celebrex	S	Oral		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown	300 Milligram Daily;	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram Daily;	Not Reported
Hydroxychloroquine /00072603/	S	Unknown	300 Milligram Daily;	Not Reported
Hydroxychloroquine /00072603/	S	Unknown	200 Milligram Daily;	Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Apo-Gabapentin	C	Oral		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Apo-Prednisone	C	Unknown		Not Reported
Apo-Prednisone	C	Oral	15 Milligram Daily;	Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported
Atorvastatin Calcium	C	Oral	40 Milligram Daily;	Not Reported
Cipralex /01588501/	C	Unknown		Not Reported
Citalopram Hydrobromide	C	Unknown		Not Reported

Conjugated Estrogens	C	Oral		Not Reported
Cymbalta	C	Unknown	120 Milligram Daily;	Not Reported
Cymbalta	C	Unknown	120 Milligram Daily;	Not Reported
Cymbalta	C	Unknown		Not Reported
Escitalopram	C	Unknown		Not Reported
Estrace	C	Unknown		Not Reported
Gabapentin	C	Unknown		Not Reported
Gabapentin	C	Oral		Not Reported
Hydrochlorothiazide	C	Oral		Not Reported
Hydromorphone Hydrochloride	C	Oral	60 Milligram Daily;	Not Reported
Hydromorphone Hydrochloride	C	Oral	6 Milligram Daily;	Not Reported
Mupirocin	C	Topical		Not Reported
Pantoloc /01263201/	C	Unknown	20 Milligram Daily;	Not Reported
Prednisone	C	Unknown	15 Milligram Daily;	Not Reported
Prednisone	C	Oral	15 Milligram Daily;	Not Reported
Prednisone	C	Oral		Not Reported
Shark Liver Oil	C	Unknown		Not Reported
Tapentadol Hydrochloride	C	Unknown		Not Reported
Taro-Mupirocin	C	Topical		Not Reported
Tramacet	C	Oral		Not Reported
Tramadol Hydrochloride	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112902	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145621		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gastric Disorder; Gingival	Methotrexate			S	Unknown			Barr
	Actemra			S	Oral			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported

Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Off Label Use; Rash; Syncope; Urticaria	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;	Not Reported
	Prevacid	C	Unknown	60 Milligram Daily;	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112903	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1145650		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Pain; Peripheral Swelling; Therapy Non-Responder	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	8 Mg/Kg Daily;		Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112920	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145746		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Mirtazapine			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17112995	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145057			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Lock; Pain In Extremity; Psoriatic Arthropathy; Synovitis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Calcium			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actonel			C				Not Reported
	Depo-Medrol			C				Not Reported

	Depo-Medrol	C			Not Reported
	Ergocalciferol	C		2000 Dosage Forms Daily;	Not Reported
	Orencia	C	Intravenous (not otherwise specified)		Not Reported
	Otezla	C			Not Reported
	Prednisone	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Dec-2019	17113075	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145734		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C		7.5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	13045102	EXPEDITED (15-DAY)		OT	CA-ROCHE-1869641		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Folinic Acid	C	Unknown	Not Reported
	Apo-Hydroxyquine	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Leucovorin [Folinic Acid]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	15628419	EXPEDITED (15-DAY)		HO, OT	CA-ASTELLAS-2018US049166		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer; Thrombosis	Tacrolimus			S	Unknown	Unk Unk, Unknown Freq.		Astellas
	Cellcept /01275102/			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Imuran /00001501/			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Plaquenil /00072602/			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			C	Unknown	Unk Unk, Unknown Freq.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16000467	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016832			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Nausea; Rheumatoid Arthritis; Swelling	Methotrexate			S	Intramuscular			Barr
	Adalimumab			S	Subcutaneous			Not Reported

	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Mefenamic Acid	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Arthrotec	C	Unknown	100 Milligram Daily;	Not Reported
	Tylenol /00020001	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16010306	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016833			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16015826	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1017617		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Ciclosporin			S	Unknown			Ivax

Treatment Failure	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Oral	Barr
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16027828	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019034		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16027969	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019700		52 YR	Female	CAN

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

Condition Aggravated; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate	S	Oral	Barr
	Methotrexate	S	Intramuscular	Barr
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Oral	Not Reported
	Asa	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Lantus	C	Subcutaneous	Not Reported
	Lozide	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Naprosyn	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16033202	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Methotrexate			S	Subcutaneous			Barr
	Azathioprine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Amoxicillin Trihydrate/Clavulanate Potassium	C			Not Reported
	Amoxil	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16044426	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1018980		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16425226	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-210555		35 YR	Female	USA

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

Haematuria; Phospholipidosis; Proteinuria	Hydroxychloroquine	S	Unknown	Unk		Sun
	Azathioprine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	16859793	EXPEDITED (15-DAY)		OT	CA-ROCHE-1844081		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Diarrhoea; Heart Rate Increased; Hypertensive Crisis; Nausea; Pneumonia; Pneumonitis; Vomiting	Rituxan			S	Intravenous (not otherwise specified)	Last Infusion: 29/May/2019		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			C				Not Reported
	Prednisone			C				Not Reported
	Effexor			C				Not Reported
	Tylenol			C	Oral			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Oral			Not Reported
	Solumedrol			C	Intravenous (not otherwise specified)			Not Reported
	Vit D			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17011158	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1132830		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Limb Deformity; Malaise; Osteoporosis; Pain; Rash; Synovitis	Naproxen Sodium			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
Cosentyx	S	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Methotrexate	C	Unknown			Not Reported
Acetaminophen/Codeine	C	Unknown			Not Reported
Celebrex	C	Unknown	2 Dosage Forms Daily;		Not Reported
Insulin	C	Unknown			Not Reported
Metformin	C	Unknown	4 Dosage Forms Daily;		Not Reported
Tylenol	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17053752	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2019M1110466		28 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Albumin Decreased; Blood Pressure Increased; Generalised Oedema; Lupus Nephritis; Maternal Exposure During Pregnancy; Pre-Eclampsia; Premature Delivery; Protein Total; Proteinuria; Weight Increased	Azathioprine			S	Unknown	100 Milligram, Qd		Not Reported
	Magnesium Sulfate			S	Intravenous (not otherwise specified)	Bolus Dose 2 G, Then Infusion Of 1.5 G/H		Mylan
	Labetalol			S	Intravenous (not otherwise specified)	50-100 Mg/8 H		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Mylan
	Methylprednisolone			S	Unknown	60 Milligram, Qd		Mylan
	Vitamin D /00107901/			C		Unk		Mylan
	Prednisone			C		5 To 10 Mg Per Day		Mylan
	Prednisone			C	Unknown	5 Milligram, Qd		Mylan
	Folic Acid			C	Unknown	Unk		Mylan
	Calcium			C	Unknown	Unk		Mylan
	Betamethasone			C	Intramuscular	2 Doses		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17113464	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-076306		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adrenal Disorder; Amnesia; Arthralgia; Asthma; Blood Pressure Increased; Bronchitis; Burning Sensation; Cough; Diarrhoea; Dysgeusia; Dyspnoea; Emotional Distress; Emphysema; Fatigue; Furuncle; Genital Herpes Simplex; Head Injury; Headache; Herpes Virus Infection; Hypertension; Inflammation; Injection Site Erythema; Injection Site Induration; Injection Site Inflammation; Injection Site Pruritus; Insomnia; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Respiratory Failure; Rhinorrhoea; Secretion Discharge; Sleep Disorder; Urine Odour Abnormal; Weight Increased	Quetiapine			S	Unknown	Unk		Aurobindo
	Actemra			S	Subcutaneous	162 Milligram, Every Week		Not Reported
	Actemra			S	Subcutaneous	162 Milligram, Every Week		Not Reported
	Actemra			S	Subcutaneous	162 Milligram, Every Week		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Every Week		Not Reported
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Once A Day		Not Reported
	Alendronate Sodium			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Ativan			C	Unknown	Unk, As Required		Not Reported
	Liptor			C	Unknown	Unk		Not Reported
	Methadone			C	Oral	10 Milligram, Once A Day		Not Reported
	Pantoloc			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Valtrex			C	Unknown	Unk		Not Reported
	Zopiclone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17113706	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145939			Female	CAN

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

Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate	S	Unknown			Barr
	Actemra	S	Subcutaneous			Not Reported
	Arava	S	Unknown			Not Reported
	Bacitracin/Neomycin Sulfate/Polymyxin B Sulfate	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/	S	Unknown			Not Reported
	Prednisone	C	Intramuscular			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114110	EXPEDITED (15-DAY)		OT	CA-SA-2019SA336230			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Sanofi
	Arava			S	Oral	Unk		Sanofi
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Not Specified (1 Mg)		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg,1 In 1 D		Sanofi
	Methotrexate			S	Intra-arterial	Not Specified (25 Mg,1 In 1 D)		Not Reported
	Prednisone			S	Unknown	Not Specified		Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Sulfasalazine			S	Unknown	2 Gm (1 Gm,2 In 1 D)		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Enbrel	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Subcutaneous	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Hydroxychloroquine Phosphate	S	Unknown	400 Mg, Qd		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114173	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145946		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral	20 Mg, 1 Every 1 Week		Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C	Oral			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114180	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145947			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Frequent Bowel Movements; Rash; Retinal Toxicity; Stomatitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	Solution		Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114182	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1146253			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Urine Abnormal; Cutaneous Sarcoidosis; Drug Ineffective; End Stage Renal Disease; Ocular Sarcoidosis; Proteinuria; Pulmonary Sarcoidosis	Methotrexate			S	Unknown	Solution		Barr
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114183	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1146091		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown	Solution		Barr
	Minocycline			S	Unknown			Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Thrombosis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Marijuana	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ilaris Single-Use Vial	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114184	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145955			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114321	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145896		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C				Not Reported
	Enablex			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported
	Loperamide			C				Not Reported
	Norflex			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported
	Pantoprazole Sodium Anhydrous			C				Not Reported
	Synthroid			C	Unknown			Not Reported
	Vagifem			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114661	NON-EXPEDITED			US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-224672			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114780	EXPEDITED (15-DAY)		HO, OT	JP-APPCO PHARMA LLC-2077490		69 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilic Pneumonia Acute	Hydroxychloroquine Sulfate			S	Oral			Appco Pharma
	Betamethasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17114880	EXPEDITED (15-DAY)		HO, OT	TW-APPCO PHARMA LLC-2077491		27 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Progressive Multifocal Leukoencephalopathy	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17115035	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145979			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Joint Stiffness; Nausea; Pain; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17115037	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145983		68 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure; Visual	Methotrexate			S	Unknown			Barr

Impairment	Hydroxychloroquine		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17115049	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145890		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C				Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C				Not Reported
	Gabapentin			C	Oral			Not Reported
	Nitroglycerin			C				Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17115051	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145899		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration;	Methotrexate			S	Oral			Barr
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Injury; Malignant Melanoma; Product Dose Omission	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine /00072603/	S	Oral	400 Milligram Daily;	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Restasis	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17115052	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145987		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Oral	10 Milligram Daily;		Not Reported
	Aspirin			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported

	Synthroid			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17115225	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019519686		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Off Label Use; Product Use Issue; Product Use Issue; Rheumatoid Arthritis; Sciatica	Methotrexate Sodium			S	Subcutaneous	25 Mg, Every 1 Week(S)		Unknown
	Acetaminophen			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Prednisone			S		7 Mg, Every 24 Hour(S)		Not Reported
	Apo-Ramipril			S		1 Every 24 Hour(S)		Not Reported
	Folic Acid			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		400 Mg, Every 24 Hour(S)		Not Reported
	Levothyroxine			S		1 Every 24 Hour(S)		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetaminophen;Codeine			C		Unk		Not Reported
	Acetaminophen;Caffeine;Dihydrocodeine Bitartrate			C		Unk		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Ophthalmic	2 Every 1 Day(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		400 Mg, Every 24 Hour(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17115477	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145937			Female	CAN

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

Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C	Unknown	Not Reported
	Omnaris	C	Unknown	Not Reported
	Ativan	C	Unknown	Not Reported
	Darifenacin	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Diphenhydramine	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Loperamide	C	Unknown	Not Reported
	Norflex	C	Unknown	Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17115531	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1119604		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus Enteritis; West Nile Viral Infection	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	As Part Of A Regimen That Involved Tapering Of The Dose		Not Reported

Rituximab	S	Unknown	Unk		Mylan
Methylprednisolone	S	Unknown	High-Dose		Mylan
Cotrimoxazole	C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17116698	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1146476		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscular Weakness; Myalgia; Peripheral Sensorimotor Neuropathy	Atorvastatine			S	Oral	40 Mg		Teva
	Doxycycline			S	Oral	200 Mg		Actavis
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	3 Dosage Form		Not Reported
	Tavanic 500 Mg, Comprime Pellicule Secable			S	Oral	1 Dosage Form		Not Reported
	Metronidazole			S	Oral	1500 Mg		Not Reported
	Lansoprazole			C	Oral	15 Mg		Not Reported
	Clopidogrel Base			C	Oral	75 Mg		Not Reported
	Fluconazole			C	Oral	200 Mg		Not Reported
	Ceftriaxone Base			C	Intravenous (not otherwise specified)	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17116982	EXPEDITED (15-DAY)		OT	NVSC2019CA054057		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Panniculitis; Product Use In Unapproved Indication	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Tofacitinib			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17117311	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145884		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown	1.8 Percent Daily;		Not Reported
	Furosemide			C	Unknown	40 Milligram Daily;		Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram Daily;		Not Reported
	Valsartan			C	Unknown	320 Milligram Daily;		Not Reported
	Xalatan			C	Unknown	50 Milligram Daily;		Not Reported
	Zingiber Officinale			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17117322	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-113478			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

Cortisone Acetate	S	Unknown	Unk		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Folic Acid	S	Unknown	5 Milligram		Not Reported
Fosamax	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17117560	NON-EXPEDITED			US-NEOPHARMA INC-000252			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Urticaria	Augmentin			S				Neopharma
	Lyrica			S	Oral	Take 1 Capsule Per Oral 4 Times A Day		Not Reported
	Cymbalta			S				Not Reported
	Methotrexate			S				Not Reported
	Morphine			S				Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Dec-2019	17118141	EXPEDITED (15-DAY)		LT	CA-TEVA-2019-CA-1145959		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-	Methotrexate			S	Unknown			Barr

Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S		Not Reported
	Sodium Aurothiomalate Injection Bp	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	9248366	EXPEDITED (15-DAY)		OT	FR-SANOFI-AVENTIS-2013SA038588		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Antinuclear Antibody Positive; Bicytopenia; Dermatitis Psoriasiform; Dna Antibody; Drug Ineffective; Evans Syndrome; General Physical Health Deterioration; Hypergammaglobulinaemia; Lymphadenopathy; Pericarditis; Pyrexia; Scar; Skin Lesion; Subacute Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
	Omeprazole			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk,Unk		Sanofi
	Mycophenolate Mofetil			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	11683978	EXPEDITED (15-DAY)		OT	PHHY2015GB136731		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Iron Deficiency; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Humira			S	Unknown	40 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	12809314	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2016037802		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported

Celebrex	S		Unk	Not Reported
Cellcept	S		Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Leflunomide	S		Unk	Not Reported
Methotrexate Sodium	S		1 Ml, Weekly (Qw)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	S		7 Mg, Once Daily (Qd)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Gold	S		Unk	Not Reported
Plaquenil	S		Unk	Not Reported
Hydroxychloroquine	S			Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Mycophenolate Mofetil	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	12923504	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1632295			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

Orencia	S	Intravenous (not otherwise specified)		Not Reported
Humira	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous	Pre-Filled Syringe	Not Reported
Simponi	S	Subcutaneous		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Anakinra	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Mycophenolate Mofetil	S	Unknown		Not Reported
Abatacept	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	13645771	EXPEDITED (15-DAY)		OT	CA-ROCHE-1947729		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Mass Excision; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 9 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	13984922	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-083241			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	14311574	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050883		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis;	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported

Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Apo-Leflunomide	S	Unk	Not Reported
	Methotrexate Sodium	S	Unk	Not Reported
	Orencia	S	Unk	Not Reported
	Desoximetasone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	14813831	NON-EXPEDITED			US-PFIZER INC-2018170458		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Dizziness; Drug Intolerance; Gastrointestinal Disorder; Headache; Nausea; Tuberculin Test Positive	Methotrexate Sodium			S	Unk			Pfizer
	Plaquenil			S	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	14824752	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110723		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Other			Not Reported
	Methotrexate			S	Other			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	15333427	EXPEDITED (15-DAY)		DS	CA-ROCHE-2175438		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Condition Aggravated; Drug Ineffective; Gastrointestinal Disorder; Impaired Work Ability; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Duloxetine Hydrochloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	15619732	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105993			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported

Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Qwk	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, Qwk	Not Reported
	Hydroxychloroquine	S	Oral	5 Mg/Kg, Qd	Not Reported
	Immunoglobulin Human Normal	S	Intravenous (not otherwise specified)	3 Mg/Kg, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg, Qwk	Not Reported
	Infliximab	S	Unknown	5 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2, Qwk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Prednisone	S	Oral	5 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5.0 Milligram/Kilogram, Qd	Not Reported
	Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Humira	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	15635117	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105457			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased;	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qmo		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown	Unk		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported

Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, Qwk	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
	Enbrel	S	Subcutaneous	12.5 Milligram, Qwk (4 Every 1 Week)	Not Reported
	Hydroxychloroquine	S	Oral	5 Mg/Kg, Qd	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Infliximab	S	Unknown	5 Mg, Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	S	Oral	1.3 Milligram, Qd (2 Every 1 Day)	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Q2wk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, Qd	Not Reported

	Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Gamastan	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Apo Naproxen	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Qd (2 Every 1 Day)	Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, Qd (2 Every 1 Day)	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unk	Not Reported
	Triamcinolone Acetonide	S	Unknown		Not Reported
	Triamcinolone Acetonide	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular	Unk	Not Reported
	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)	1 Df, Qwk	Not Reported
	Triamcinolone	S	Subcutaneous	25 Milligram, Q2wk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	15846816	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001282			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Arthropathy; Blood Cholesterol Increased; Breast Cancer; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Hand Deformity; Headache; Herpes Zoster; Infection; Infection; Joint Swelling;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram Daily;		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	400 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported

Leukopenia; Liver Function Test Abnormal; Loss Of Consciousness; Pain In Extremity; Peripheral Swelling; Pneumonia Viral; Rheumatoid Arthritis; Rheumatoid Arthritis; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete; Vomiting	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Anakinra	C	Unknown		Not Reported
	Anakinra	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Arava	C			Not Reported
	Ativan	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Darifenacin Hydrobromide	C	Unknown		Not Reported

	Dexamethasone	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Benadryl	C	Unknown		Not Reported
	Furosemide	C	Unknown	120 Milligram Daily;	Not Reported
	Hydromorphone	C	Unknown		Not Reported
	Kadian	C	Unknown		Not Reported
	Loperamide	C	Unknown		Not Reported
	Norflex /00018303/	C	Unknown		Not Reported
	Omnaris	C	Unknown		Not Reported
	Oxyneo	C	Unknown		Not Reported
	Pantoloc	C	Unknown		Not Reported
	Restasis	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Kenalog /00031902/	C	Intra-articular		Not Reported
	Trimethoprim	C	Unknown		Not Reported
	Urispas	C	Unknown		Not Reported
	Vagifem	C	Unknown		Not Reported
	Desoximetasone	C	Intramuscular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	15925771	EXPEDITED (15-DAY)		OT	CA-ROCHE-2260693		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	16033405	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019340		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	16045302	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020374		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder;	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intravenous (not otherwise specified)			Barr

Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown	20 Milligram Daily;	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	16059282	EXPEDITED (15-DAY)		DE, HO	CA-TEVA-2019-CA-1021632		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Infection; Escherichia Infection; Strongyloidiasis; Strongyloidiasis	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	Various Doses		Actavis
	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	16059882	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1020742		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Codeine Phosphate			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Actavis
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Ramipril			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
Levothyroxine	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Prednisone	S	Unknown	7 Milligram Daily;	Actavis
Prednisone	S	Unknown		Actavis
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Cosopt	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Tylenol	S	Unknown		Not Reported
Acetaminophen/Caffeine	C	Unknown		Not Reported
Plaquenil	C	Unknown	400 Milligram Daily;	Not Reported
Tylenol 2	C	Unknown		Not Reported
Acetaminophen/Caffeine/Dihydrocodeine	C	Unknown		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Milligram Daily;	Not Reported
Tylenol/00020001/	C	Unknown		Not Reported
Acetaminophen	C	Unknown		Not Reported
Caffeine	C	Unknown		Not Reported
Codeine	C	Unknown		Not Reported
Dorzolamide Hydrochloride	C	Ophthalmic		Not Reported
Folic Acid	C	Unknown		Not Reported
Levothyroxine	C	Unknown		Not Reported
Meprobamate	C	Unknown		Not Reported
Prednisone	C	Unknown	7 Milligram Daily;	Not Reported

	Ramipril	C	Unknown	Not Reported
	Timolol Maleate	C	Ophthalmic	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	16069616	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022918		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Amoxicillin Sodium/Clavulanate Potassium			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Clavulin			S	Unknown			Not Reported
	Plaquenil/00072602/			C	Unknown	400 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	7.5 Milligram Daily;		Not Reported
	Tridural			C	Unknown			Not Reported
	Tylenol/00020001/			C	Unknown			Not Reported
	Plaquenil (Hydroxycholroquine Sulfate)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	16081129	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022928		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Methylprednisolone			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Rituxan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	16193605	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036909		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Hormone Level Abnormal; Immobile; Intentional Product Misuse; Loss Of Personal Independence In Daily Activities; Menopausal Symptoms; Menopause; Mobility Decreased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Oral	10 Mg, 1 Every 1 Week,		Barr
	Methotrexate			S	Oral	20 Mg, 1 Every 1 Week,		Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral	10 Mg, 1 Every 1 Week,		Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported
	Arava			S	Unknown	20 Milligram Daily; Duration- 2 Years		Not Reported
	Enbrel			S	Unknown	50 Mg,		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Duration- 5 Years		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	1 Dosage Forms		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Mefenamic Acid			S	Unknown	800 Milligram Daily;		Not Reported
	Mefenamic Acid			S	Unknown	800 Milligram Daily;		Not Reported
	Mefenamic Acid			S	Unknown	800 Milligram Daily;		Not Reported
	Plaquenil			S	Oral	400 Milligram Daily; Duration-730		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	16498662	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019026467		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Contraindicated Product Administered; Drug Intolerance; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Solution Subcutaneous		Ucb
	Enbrel			S	Subcutaneous	1 Dosage Form, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Lyrica			C		Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17118621	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201912002578			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira 40mg/0.4ml(40 Milligram)			S	Subcutaneous	40 Mg (1 In 2 Weeks)		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17118631	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201912002577			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Injury	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira 40mg/0.4ml			S	Subcutaneous	40mg/0.4ml, 40 Mg (1 In 2		Not Reported

			Week)		
	Pravastatin Sodium	C	10 Mg		Not Reported
	Zetia	C	10 Mg		Not Reported
	Arava	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17118701	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488466		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Azathioprine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17119744	EXPEDITED (15-DAY)		OT	CA-ROCHE-2483689			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17119954	EXPEDITED (15-DAY)		OT	CA-ROCHE-2484475			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17119955	EXPEDITED (15-DAY)		OT	CA-ROCHE-2486166		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17120611	EXPEDITED (15-DAY)		OT	CA-ROCHE-2483718		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17120642	EXPEDITED (15-DAY)		OT	CA-ROCHE-2483749		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Actemra			S	Subcutaneous			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

	Enbrel			S	Unknown		Not Reported
	Lyrica			S	Unknown		Not Reported
	Methotrexate			S	Unknown		Not Reported
	Orencia			S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)		Not Reported
	Simponi			S	Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17120769	EXPEDITED (15-DAY)		HO	DK-MYLANLABS-2019M1120144		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Mycoplasmal	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Mylan
	Insulin			C	Unknown	On A Pump		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17120794	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051770		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S		4.0 Mg/Kg		Not Reported
	Adalimumab			S				Not Reported
	Celebrex			C				Not Reported
	Diclofenac			C				Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

	Hydroxychloroquine	S		200 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S		200 Milligram, 2x/Day (Bid)	Not Reported
	Leflunomide	S		20 Milligram, Once Daily (Qd) For 6 Months	Not Reported
	Lyrica	C		Unk	Not Reported
	Methotrexate	C	Subcutaneous	20 Milligram, Weekly (Qw)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram For 6 Years	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	C			Not Reported
	Tocilizumab	S			Not Reported
	Valsartan	C			Not Reported
	Xeljanz	C	Oral	5 Milligram, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17120847	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145985			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17120943	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145984			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib			S	Subcutaneous	10 Milligram Daily;		Not Reported
	Tofacitinib			S	Unknown	20 Milligram Daily;		Not Reported
	Celebrex			C	Oral			Not Reported
	Ibuprofen			C	Oral			Not Reported
	Lipitor			C	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17121205	EXPEDITED (15-DAY)		OT	US-UCBSA-2017020170			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Pruritus; Rash; Rheumatoid Arthritis	Cimzia			S		Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Weekly (Qw)		Not Reported

	Enbrel	S		Unk	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Folic Acid	C	Oral	3 Mg, Once Daily (Qd)	Not Reported
	Nexium	C	Oral	20 Mg Daily	Not Reported
	Tofacitinib	C	Oral	11 Mg, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17121430	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2019M1118994		29 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Coronary Syndrome; Heart Transplant; Nephrotic Syndrome; Renal Transplant	Methylprednisolone			S	Unknown	5000 Milligram		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Azathioprine			S	Unknown	2 Milligram/Kilogram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Ramipril			C	Unknown	5 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17121462	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1146153		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17121496	EXPEDITED (15-DAY)		OT	DE-GLAXOSMITHKLINE-DE2019218576		54 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Benlysta			S		Unk		Glaxosmithkline
	Prednisolon			S		Unk		Glaxosmithkline
	Quensyl			S		5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17121577	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1146246		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Fatigue; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity; Rash	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17121826	EXPEDITED (15-DAY)		HO	NVSC2019US058006		51 YR	Male	USA

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

Dyspnoea; Mycobacterium Avium Complex Infection; Productive Cough; Pyrexia	Mycophenolate Mofetil	S	Unknown	1000 Mg, Bid	Novartis
	Prednisone	S	Unknown	10 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Fluticasone W/Salmeterol	S	Unknown	1 Df, Bid (1 Inhalation Twice Daily)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17121830	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007679		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Enbrel			S	Unknown	50 Milligram Daily;		Not Reported
	Leflunomide			S	Unknown			Barr
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported

	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S		2 Gram Daily;	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Rituxan	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17121916	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1146206		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17123737	EXPEDITED (15-DAY)		OT	CA-ROCHE-2486162		62 YR	Female	CAN

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

Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Meloxicam	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17123744	EXPEDITED (15-DAY)		OT	CA-ROCHE-2485939		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Pantoprazole Sodium Sesquihydrate			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported

	Tenofovir	C	Unknown	Not Reported
	Tenofovir Disoproxil	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17123823	EXPEDITED (15-DAY)		DS	CA-ROCHE-2486210			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17124330	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1146711		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Contraindicated	Methotrexate Sodium			S	Oral			Barr

Product Administered; Gait Disturbance; Multiple System Atrophy; Rheumatoid Arthritis	Methotrexate Sodium	S	Oral			Barr
	Methotrexate Sodium	S	Subcutaneous			Barr
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17124829	EXPEDITED (15-DAY)		OT	CA-SHIRE-CA201941459			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Placental Insufficiency; Premature Delivery	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	Unk		Shire
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17125168	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488200		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-	Rituxan			S	Intravenous drip			Not Reported

Hodgkin'S Lymphoma	Apo-Azathioprine	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Amoxicillin Sodium;Clavulanate Potassium	C	Unknown	Not Reported
	Amoxil [Amoxicillin]	C	Unknown	Not Reported
	Bcg Vaccine	C	Intravenous (not otherwise specified)	Not Reported
	Bcg Vaccine	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17125177	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488687		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17125178	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488231		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17125220	EXPEDITED (15-DAY)		HO	CA-ROCHE-2485004		26 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Incompetence; Asthenia; Chest Discomfort; Drug Ineffective; Dyspnoea; Headache; Heart Rate Increased; Hyperhidrosis; Left Ventricular Dilatation; Myocarditis; Nausea; Nephritis; Pleuritic Pain; Systemic Lupus Erythematosus; Treatment Failure; Vasculitis	Mycophenolate Mofetil			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Colchicine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Dec-2019	17125230	EXPEDITED (15-DAY)		OT	CA-ROCHE-2486098		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis	Actemra			S	Unknown	3.0 Year(S)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	9.0 Month(S)		Not Reported
	Arava			S	Oral	9.0 Month(S)		Not Reported
	Arava			S	Oral	9.0 Month(S)		Not Reported
	Cimzia			S	Subcutaneous	2.0 Year(S). Single-Use Prefilled Syringe		Not Reported
	Diclofenac Sodium/Misoprostol			S	Unknown	2.0 Year(S)		Not Reported
	Enbrel			S	Unknown	730.0		Not Reported
	Enbrel			S	Unknown	4.0 Year(S)		Not Reported
	Enbrel			S	Unknown	731.0		Not Reported
	Humira			S	Subcutaneous	5.0 Month(S)		Not Reported

Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown	1.0 Month(S)	Not Reported
Leflunomide	S	Unknown	5.0 Month(S)	Not Reported
Methotrexate	S	Subcutaneous	8.0 Year(S)	Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	2.0 Year(S)	Not Reported
Simponi	S	Subcutaneous	2.0 Month(S)	Not Reported
Arthrotec	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Gold	C	Unknown		Not Reported
Imuran [Azathioprine]	C	Unknown		Not Reported
Vitamin D [Colecalciferol]	C	Unknown		Not Reported
Vitamin D3	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	12076304	EXPEDITED (15-DAY)		DS	CA-ROCHE-1678552		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	For 2 Years		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Remicade	S	Subcutaneous			Not Reported
Xeljanz	S	Unknown			Not Reported
Xeljanz	S	Oral			Not Reported
Xeljanz	S	Oral	Theraoy Duration -158.0 Nos		Not Reported
Cimzia	S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
Orencia	S	Subcutaneous	Therapy Duration: 3.0 Year(S)		Not Reported
Prednisone	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	14309271	EXPEDITED (15-DAY)		DS, HO, OT	CA-UCBSA-2017050897		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Sulfasalazine			S		500 Mg		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tofacitinib			S		5 Mg, Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Infliximab			S				Not Reported
	Orencia			C		Unk		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unk	Not Reported
	Xeljanz	S	5 Milligram, 2x/Day (Bid)	Not Reported
	Arava	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	16053731	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023712		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Oral			Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	16058867	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020935			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Reactine (Cetirizine)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	16059884	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020671			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral	10 Milligram Daily;		Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	16060796	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1024063			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Methotrexate			S	Oral			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Oral	400 Milligram Daily;		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	16961068	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019043848		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Crohn'S Disease; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Gastrointestinal Disorder; Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Skin	Cimzia			S	Subcutaneous	200 Milligram, Solution Subcutaneous		Not Reported
	Apo-Leflunomide			S		5 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram; Solution For Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S		5 Milligram		Not Reported
	Methotrexate			S		5 Milligram		Not Reported
	Orencia			S		750 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported

Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Tuberculin Test Positive; Urinary Tract Infection	Actemra	S		Unk	Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram	Not Reported
	Arava	S		Unk	Not Reported
	Hydroxychloroquine	S		5 Milligram	Not Reported
	Leflunomide	S	Oral	10 Milligram	Not Reported
	Leflunomide	S		5 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	5 Milligram	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Prednisone	C		50 Milligram, Once Daily (Qd)	Not Reported
	Gold	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	17125243	EXPEDITED (15-DAY)		OT	CA-ROCHE-2486138		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration 13.0 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	17125248	EXPEDITED (15-DAY)		OT	CA-ROCHE-2486257		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2019	17125249	EXPEDITED (15-DAY)		OT	CA-ROCHE-2486415		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Therapy Duration:- 10.0 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			C	Oral	Therapy Duration:- 13.0 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	15940202	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010066		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported

	Leucovorin /00566701/	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16009439	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016503		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Osteoarthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16044415	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019798		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr

Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
Otezla	S	Unknown	60 Milligram Daily;		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Prednisone	C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16045316	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020425		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Orencia			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Aspirin			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16047237	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020897			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Other			Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16049926	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020688			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine		S	Unknown		Not Reported
	Tocilizumab		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported
	Apo-Leflunomide		S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe		C	Unknown		Not Reported
	Prednisone		C	Unknown	10.0 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16049940	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020827		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown	100.0 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25.0 Milligram		Barr
	Minocycline			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16050526	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020942		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective;	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr

Menopausal Symptoms; Musculoskeletal Stiffness; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate	S	Oral		Barr
	Apo-Leflunomide	S	Oral	20 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Mefenamic Acid	S	Unknown	800 Milligram Daily;	Not Reported
	Mefenamic Acid	S	Unknown	800 Milligram Daily;	Not Reported
	Plaquenil	S	Oral	400 Milligram Daily;	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16050530	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020786		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Imuran	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16051151	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023397			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16051154	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1023406		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased; Viral Infection	Methotrexate			S	Oral			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16054839	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020448		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown	400 Milligram Daily;		Not Reported
	Septra			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16057945	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020981		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	25milligram, 2every 1weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16058720	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020936			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16058860	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021148		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Orencia	S	Oral			Not Reported
Remicade	S	Unknown			Not Reported
Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16058882	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020905		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Chest Pain; Decreased Appetite; Drug Ineffective; Dyspnoea; Fatigue; Hypersensitivity; Malaise; Nasal Congestion; Neuralgia; Pain In Extremity; Productive Cough; Rheumatoid Arthritis; Vision Blurred; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral	20 Milligram Daily;		Barr
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	40 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Plaquenil			C	Oral	400 Milligram Daily;		Not Reported
	Prednisone			C	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16058974	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021101			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Pneumocystis Jirovecii Pneumonia; Pulmonary Fibrosis; Synovitis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16059878	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020699		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Warfarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16060463	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024077			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Headache; Hepatotoxicity; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			C	Unknown	2 Gram Daily;		Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16060509	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024084		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis;	Methotrexate			S	Unknown			Barr

Therapeutic Product Effect Incomplete	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400 Mol Daily;	Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	C	Unknown	2 Gram Daily;	Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16061828	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020940		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16062133	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1020894		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16069174	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021716			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16073284	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021434		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Methotrexate			S	Oral			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16073285	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021500		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Venlafaxine Hydrochloride			S	Oral	37.5 Milligram Daily;		Teva
	Venlafaxine Hydrochloride			C	Oral	37.5 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown	12.5 Milligram Daily;		Not Reported
	M-Eslon			C	Unknown	20 Milligram Daily;		Not Reported
	Morphine			C	Unknown			Not Reported
	Morphine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	16752157	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1097379			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Barr
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	17035514	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-107291			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	17079806	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001376			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Hepatic	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr

Enzyme Increased; Off Label Use; Pain; Pneumonia; Rheumatoid Arthritis	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Lyrica	S	Oral	300 Milligram Daily;		Not Reported
	Apo-Leflunomide	S				Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Unknown			Not Reported
	Tylenol /00020001/	C	Unknown			Not Reported
	Prednisone	C				Not Reported
	Simponi	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2019	17125718	NON-EXPEDITED			US-AMGEN-USASP2019202478		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Depo-Medrol			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	12767722	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076641		52 YR	Female	CAN

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

Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Oral	10 Milligram, 1 Every 24 Hours	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, 1 Every 24 Hours	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Methotrexate	S	Intramuscular	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram, 1 Every 24 Hours	Not Reported
	Asa	C	Unknown	81 Mg, Unk	Not Reported
	Lantus	C	Subcutaneous		Not Reported
	Lozide [Indapamide]	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	Unk	Not Reported
	Naprosyn [Naproxen]	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Ramipril	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Acetylsalicylic Acid	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	14298460	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050715		52 YR	Female	CAN

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

Arthralgia; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Off Label Use; Peripheral Swelling; Rash; Tendon Disorder; Therapeutic Response Decreased	Cimzia	S	Subcutaneous	Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Bactrim	S		Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S		200 Mg, 2x/Day (Bid)	Not Reported
	Methotrexate Sodium	S		20 Mg, Weekly (Qw)	Not Reported
	Methotrexate Sodium	S		25 Mg, Weekly (Qw)	Not Reported
	Orencia	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	14410966	EXPEDITED (15-DAY)		OT	US-UCBSA-2017008470			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Alopecia; Cardiac Disorder; Fatigue; Iron Deficiency Anaemia; Rhinorrhoea; Sjogren'S Syndrome; Suicidal Behaviour; Viral Infection	Cimzia			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Tofacitinib Citrate			S	Oral	10 Mg, Once Daily (Qd)		Not Reported
	Gold			S				Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Iron			C				Not Reported
	Sotalol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	14703375	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2018012990		46 YR	Female	CAN

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

Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Abatacept	S		Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Anakinra	S		Unk	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Mycophenolate Mofetil	S		Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Gold	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
	Sodium Aurothiomalate	S		Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Celebrex	C			Not Reported
	Humira	C			Not Reported
	Methotrexate	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	15635162	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105536		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Increased; C-Reactive	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qmo		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Intra-articular	Unk		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb

Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Triamcinolone Acetonide	S	Unknown		Bristol Myers Squibb
	Adalimumab	S	Subcutaneous		Not Reported
	Kineret	S	Subcutaneous	50 Mg, Qd	Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Enbrel	S	Subcutaneous	12.5 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Mg/Kg, Qd	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg, Qwk	Not Reported
	Infliximab	S	Unknown	5 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Milligram/Sq. Meter, 1 Every 1 Week	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Unknown	280 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown		Not Reported
	Gammagard	S	Unknown		Not Reported
	Triamcinolone	S	Subcutaneous	25 Milligram, Q2wk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	15635195	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105899		58 YR	Female	CAN

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

Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation	Orencia	S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported
	Alendronate Sodium	C	Unknown	Unk		Not Reported
	Fosamax	C	Unknown			Not Reported
	Vitamin D3	C	Unknown	Unk		Not Reported
	Ibuprofen	C	Unknown	Unk		Not Reported
	Lisinopril	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	15936038	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010077		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	16058873	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020938		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	16070053	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021612			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	16387418	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-050957			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported
	Synthroid			C	Unknown			Not Reported
	Acetaminophen			S	Unknown	325 Milligram		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Codeine			C	Unknown	Unk		Not Reported
	Acetaminophen;Codeine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	16591529	EXPEDITED (15-DAY)		OT	FI-PFIZER INC-2019307864		80 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Valve Stenosis; Blood Pressure Decreased; Cerebral Infarction; Dizziness; Drug Interaction; Labelled Drug-Drug Interaction Medication Error; Pain In Extremity; Rheumatoid Arthritis	Trexan			S	Oral	5 Df, Weekly		Pfizer
	Cardace (Ramipril)			S	Unknown	1 Df, 1x/Day		Pfizer
	Cardace (Ramipril)			S		Unk		Pfizer
	Diurex Mite			S	Oral	1 Df, 1x/Day		Not Reported
	Primaspan			S	Oral	1 Df, 1x/Day (In The Morning)		Not Reported
	Oxiklorin			S	Oral	1 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	16675382	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1086690		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Barr
	Methotrexate	C	Subcutaneous		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	16902124	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019AMR181621			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Benlysta Powder For Infusion			S	Intravenous (not otherwise specified)	600 Mg, Q4wks		Glaxosmithkline
	Benlysta Powder For Infusion			S		Unk		Glaxosmithkline
	Calcium Unknown			S	Oral	1000 Mg, 1d		Glaxosmithkline
	Levothyroxine			S	Oral	88 ?G, 1d		Glaxosmithkline
	Triamcinolone Cream			S	Topical	Unk Unk, Bid Prn		Glaxosmithkline
	Vitamin D3			S	Oral	1000 Df, Bid		Glaxosmithkline
	Alprazolam			S	Oral	Unk, Prn		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Not Reported
	Zoloft			S	Oral	1.5 Df, 1d		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17126131	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489296			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Leflunomide	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	C	Unknown		Not Reported
Wellbutrin	C	Oral		Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17127253	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-114365		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Discomfort; Rash; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Rituximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17127375	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1799		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fibromyalgia; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Methotrexate (Trade Name Unknown)			S	Oral	Strength: 2.5 Mg Tablet, 10 Mg Every Friday Am And 10 Mg Friday Pm		Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Sertraline Hcl			S	Unknown			Not Reported
	Citalopram			S	Unknown			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Indomethacin			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lidocaine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Baclofen			C	Unknown	Qhs		Not Reported
	Temazepam			C	Unknown	Qhs		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methylprednisolone Acetate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Vitamin D			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17127378	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5818		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Oxyneo			C	Unknown			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Oxycontin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17127573	EXPEDITED (15-DAY)		OT	CA-ROCHE-2486872			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Azathioprine			S	Subcutaneous			Not Reported
	Azathioprine			S	Subcutaneous			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sarilumab			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Magnesium			C				Not Reported
	Metformin			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17127629	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-114359			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deep Vein Thrombosis; Diarrhoea; Rash; Skin Infection; Systemic Lupus Erythematosus; Transaminases Increased; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not	Unk, Q6wk		Not Reported

			otherwise specified)			
	Sulfasalazine	S	Unknown			Not Reported
	Folic Acid	C	Unknown	5 Milligram, Qd		Not Reported
	Pariet	C	Unknown	20 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17128620	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019523918			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Enbrel			S	Unknown	Unk		Pfizer
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17128972	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019526097		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Rocuronium Bromide			S	Unknown			Unknown
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17128982	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051665		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Bone Erosion; Condition Aggravated; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Liver Function Test Increased; Off Label Use; Peripheral Swelling; Platelet Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Azathioprine			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Weekly (Qw)		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2x/Day (Bid)		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

	Rosuvastatin	S		Unk	Not Reported
	Rosuvastatin Calcium	S	Oral	0.5 Milligram, 2x/Day (Bid)	Not Reported
	Rosuvastatin Calcium	S		Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Allopurinol	C		200 Milligram, Once Daily (Qd)	Not Reported
	Coversyl [Perindopril Arginine]	C		Unk	Not Reported
	Cephalexin [Cefalexin]	C		500 Milligram, 4x/Day (Qid)	Not Reported
	Prednisone	C		10 Milligram, Once Daily (Qd)	Not Reported
	Xeljanz	C	Oral	5 Milligram, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17130295	EXPEDITED (15-DAY)		OT	CA-ROCHE-2486034		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actonel			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single-Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Film-Coated Tablet		Not Reported

Leflunomide	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Xeljanz	C	Unknown	Not Reported
Risedronate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17130553	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1148831			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Imuran			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira (Adalimumab)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	28.5714 Milligram Daily;		Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17130572	EXPEDITED (15-DAY)		DE, HO, LT	CA-TEVA-2019-CA-1148952			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris Single-Use Vial			S	Subcutaneous			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17130605	EXPEDITED (15-DAY)		OT	CA-ROCHE-2485962		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Arthrotec			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17130678	EXPEDITED (15-DAY)		HO, OT	NVSC2019FR056968		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Agitation; Catatonia; Cogwheel Rigidity; Cyclothymic Disorder; Delusion; Distractibility; Drug	Valproate			S	Unknown	Up To 2g/D		Novartis
	Amisulpride			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported

Ineffective; Drug Resistance; Euphoric Mood; Extrapyramidal Disorder; Hallucination, Auditory; Immobile; Insomnia; Logorrhoea; Mania; Muscle Rigidity; Mutism; Negativism; Pneumonia Aspiration; Psychomotor Hyperactivity; Salivary Hypersecretion; Tremor; Waxy Flexibility; Withdrawal Syndrome	Cyclophosphamide	S			Not Reported
	Olanzapine	S	Unknown	Up To 20 Mg/D	Not Reported
	Prednisolone	S	Unknown		Not Reported
	Prednisolone	S	Oral	Starting Dose Of 1mg/Kg Per Day	Not Reported
	Tropatepine	S	Unknown	Unk	Not Reported
	Diazepam	S	Unknown	Unk	Not Reported
	Diazepam	S	Intramuscular	10 Mg, Once/Single	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S			Not Reported
	Loxapine	S	Intramuscular	100 Mg	Not Reported
	Loxapine	S			Not Reported
	Haloperidol	S	Unknown	Unk	Not Reported
	Methylprednisolone	S	Unknown	Unk	Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)	500 Mg	Not Reported
	Cyamemazine	S	Unknown	High-Dose/ Over 3 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17130732	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2019CA026984			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	520 Mg, Unk		Not Reported
	Methotrexate Sodium			S		20 Mg, Unk		Not Reported
	Cosentyx			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Unk		Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Otezla			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17131229	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027018			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Joint Range Of Motion Decreased; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Infliximab Pfizer (Unknown)			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	1 Every 2 Weeks		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported
	Remicade			S	Unknown			Not Reported
	Acidophilus, Lactobacillus			C	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Deflazacort			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Hydromorphone Hydrochloride			C	Unknown			Not Reported
	Januvia			C	Unknown			Not Reported
	Kenalog [Triamcinolone Acetonide]			C	Unknown			Not Reported
	Lidocaine			C	Topical			Not Reported
	Metronidazole			C	Unknown	Unk		Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Pantoloc [Pantoprazole]			C	Unknown			Not Reported

Pregabalin	C	Unknown	Not Reported
Risedronate	C	Unknown	Not Reported
Rosuvastatin Calcium	C	Unknown	Not Reported
Salbutamol	C	Unknown	Not Reported
Triamcinolone	C	Unknown	Not Reported
Tylenol [Paracetamol]	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2019	17132019	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488361		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported

	Minocycline	C	Unknown	Not Reported
	Penicillamine	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tocilizumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	11449568	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2015009724		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol Ra			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Cefazolin			S		Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Oral	10 Mg, Unk		Not Reported
	Plaquenil			S		200 Mg, 2x/Day (Bid)		Not Reported

Naproxen	C	1000 Mg		Not Reported
Methotrexate	C	1 Cc		Not Reported
Amlodipine	C	5 Mg		Not Reported
Prednisone	C			Not Reported
Benadryl	C			Not Reported
Viread	C	Unk		Not Reported
Arava	C	Unk		Not Reported
Tofacitinib Citrate	C	5 Mg, 2x/Day (Bid)		Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	14308490	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017051040		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Tofacitinib Citrate			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Orencia			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide			S		Unk		Not Reported
	Xeljanz			S		5 Milligram, 2x/Day (Bid)		Not Reported
	Tofacitinib Citrate			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported

	Aspirin	C		Unk	Not Reported
	Cymbalta	C		Unk	Not Reported
	Hydromorphone	C		Unk	Not Reported
	Synthroid	C		Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	14489729	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007329		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Condition Aggravated; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Ear Pain; Facial Pain; Facial Paralysis; Fatigue; Fibromyalgia; Foot Deformity; Gait Disturbance; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Influenza Like Illness; Insomnia; Joint Range Of Motion Decreased; Lipoma; Melanocytic Naevus; Musculoskeletal Stiffness; Nasal Discomfort; Nasopharyngitis; Nausea; Night Sweats; Off Label Use; Oropharyngeal Discomfort; Osteoporosis;	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Bristol Myers Squibb
	Calcium Folinate			S	Oral	5 Milligram, Qd		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			S	Oral	5 Mg, Qd		Not Reported
	Methotrexate			S	Oral	12.5 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Qd		Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Vitamin B 12			C	Oral	1 Df, Qd		Not Reported
	Acetaminophen;Oxycodone			C	Oral			Not Reported

Pain; Pain In Extremity; Pain In Jaw; Pelvic Prolapse; Peripheral Coldness; Platelet Count Decreased; Post Procedural Infection; Rheumatoid Arthritis; Rhinorrhoea; Skin Mass; Therapeutic Product Effect Decreased; Throat Irritation	Hydrochloride Fentanyl	C	Unknown	1 Df, Unk		Not Reported
	Gabapentin	C	Oral	400 Mg, Bid		Not Reported
	Metformin Hydrochloride;Sitagliptin	C	Oral	Unk, Bid		Not Reported
	Perindopril Erbumine	C	Oral	8 Mg, Qd		Not Reported
	Rabeprazole	C	Oral	180 Mg, Qd		Not Reported
	Ranitidine	C	Oral	150 Mg, Qd		Not Reported
	Rosuvastatin Calcium	C	Oral	5 Mg, Bid		Not Reported
	Synthroid	C	Oral	1 Df, Qd		Not Reported
	Zopiclone	C	Oral	7.5 Mg, Qd		Not Reported
	Celebrex	C	Unknown	Unk, Prn		Not Reported
	Desoximetasone	C	Unknown			Not Reported
	Varicella Zoster Vaccine	C	Unknown	Unk, Total		Not Reported
	Tylenol	C	Unknown			Not Reported
	Oxycodone Hydrochloride	C	Unknown	Unk		Not Reported
	Sitagliptin	C	Oral	Unk, Bid		Not Reported
	Acetaminophen	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	15428288	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189244		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

Swelling; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	15719706	EXPEDITED (15-DAY)		OT	GB-ALLERGAN-1828272US			Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Myopathy; Orthostatic Hypotension	Risedronate Sodium Unk			S		35 Mg, Unk		Allergan
	Lipase;Amylase;Protease Unk			S		10 Mg, Tid		Allergan
	Prednisolone Unk			S		7.5 Mg, Daily		Pacific Pharma
	Domperidone Maleate			S		10 Mg, Q8hr		Not Reported
	Immunoglobulins (Immunoglobulin Human Normal)			S	Unknown	Unk		Not Reported
	Itraconazole			S	Oral	100 Mg, Qd		Not Reported
	Uniphyllin			S	Intravenous (not otherwise specified)	200 Mg, Bid Intermittent Ivig Infusions		Not Reported
	Levothyroxine Sodium			S	Unknown	75 Mg, Qd		Not Reported
	Carbocisteine			S	Unknown	750 Mg, Bid		Not Reported
	Lansoprazole			S	Unknown	30 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Iviglob-Ex			S				Not Reported
	Creon			C	Unknown	10 Mg, Tid		Not Reported
	Propranolol			C	Unknown	Unk		Not Reported
	Theophylline			C		200 Mg, Bid		Not Reported
	Pancreatin			C		10 Mg, Q8hr		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	16070493	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024279		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Advil			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	16079633	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022682			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Minocycline			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)		
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	16079691	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022334			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Butterfly Rash; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Oral			Barr
	Prednisone			S	Unknown			Actavis
	Prednisone			S				Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

Golimumab	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Subcutaneous		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Phthalylsulfathiazole	S			Not Reported
Plaquenil /00072602/	S	Unknown	400 Milligram Daily;	Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Reactine /00884302/	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S			Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfathalidine	S	Unknown		Not Reported
Winpred	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S			Not Reported
Diclofenac	C	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Prednisolone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	16811034	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

BMS-2019-087035

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Topical	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Subcutaneous	1 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Topicort [Desoximetasone]			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17046198	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201911001747			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Synovitis	Hydroxychloroquine			S	Unknown	200 Mg, Bid Film-Coated Tablet		Concordia
	Methotrexate			S	Unknown	20 Mg, Weekly, Once In A Week		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17063408	EXPEDITED (15-DAY)		DE, HO	US-ZYDUS-043320		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspergillus Infection; Escherichia Infection; Haemophagocytic Lymphohistiocytosis; Pseudomonas Infection; Pyrexia; Skin Lesion	Hydroxychloroquine			S		Mixed Connective Tissue Disorder		Zydus Pharm
	Prednisone			S				Not Reported
	Rituximab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17132205	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489266			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Diclofenac	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17132363	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489219			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz	S	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Leflunomide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17132537	EXPEDITED (15-DAY)		HO	DK-ACCORD-164185		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; C-Reactive Protein Increased; Fatigue; Joint Swelling; Off Label Use; Weight Decreased	Methotrexate			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17132694	EXPEDITED (15-DAY)		DS	CA-ROCHE-2489243		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Bupropion			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C				Not Reported

	Naproxen			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17133078	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051809		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Actonel			S				Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Arava			S				Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Prednisolone			S				Not Reported
	Prednisone			S				Not Reported
	Simponi			S	Subcutaneous	Solution, Subcutaneous		Not Reported
	Sulfasalazine			S	Oral	500 Milligram		Not Reported
	Cyclobenzaprine			C		10 Milligram		Not Reported
	Desoximetasone			C		5 Milligram, Once Daily (Qd)		Not Reported
	Desoximetasone			C		5 Unk		Not Reported
	Leflunomide			C				Not Reported
	Prednisone Acetate			C		5 Milligram, Once Daily (Qd)		Not Reported
	Tylenol [Paracetamol]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17133101	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488057		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17133534	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488643		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17133920	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20191207495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting	Motrin			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Aspirin /00002701/			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold (198 Au) Colloidal			S	Other			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported
	Vitamin C /00008001/			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17133976	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489342		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Rheumatoid Arthritis	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134009	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489360		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Weight Decreased	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134176	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051895		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Arava			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Oral	25 Milligram, Weekly (Qw)		Not Reported

	Morphine Sulfate	S			Not Reported
	Sulfasalazine	S	1000 Milligram, 2x/Day (Bid)		Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134324	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051892			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Nausea; Retinal Disorder; Rheumatoid Arthritis; Vomiting	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil Sulfate			S				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Isoniazid;Pyridoxine Hydrochloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134410	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489289			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134454	EXPEDITED (15-DAY)		OT	CA-ROCHE-2487298		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Endocervical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	3.0 Year(S)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134515	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051845			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Off Label Use; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Orencia			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134543	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019526632		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel			S		50 Mg, Unk		Pfizer
	Methotrexate Sodium			S		5 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Mg, Unk		Not Reported
	Leflunomide			S	Oral	5 Mg, Unk		Not Reported
	Orencia			S		750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134648	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5882		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported

Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Enbrel	S	Unknown	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134891	EXPEDITED (15-DAY)		LT	CA-ROCHE-2485918		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction;	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Humira	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Marijuana	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S		Not Reported

	Kineret	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134894	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051860		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchitis; C-Reactive Protein Increased; Colitis; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pneumonia; Product Dose Omission; Rheumatoid Arthritis; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Thyroid Disorder; Treatment Failure; Vomiting	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S		50 Milligram, Weekly (Qw)		Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		400 Milligram		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S		15 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		15 Milligram		Not Reported
	Orencia			S				Not Reported
	Actemra			S		1 Dosage Form		Not Reported
	Arava			S				Not Reported
	Baclofen			C				Not Reported
	Calcium			C				Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C				Not Reported
	Ergocalciferol			C				Not Reported
	Estradiol			C				Not Reported
	Estrogel			C				Not Reported
	Furosemide			C				Not Reported
	Levaquin			C				Not Reported
	Morphine			C				Not Reported
	Potassium Chloride			C				Not Reported
	Valsartan			C				Not Reported
	Xalatan			C				Not Reported
	Zingiber Officinale			C				Not Reported
	Gravol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17134922	EXPEDITED (15-DAY)		CA, OT	NVSC2019DE058830		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Hand Malformation; Developmental Hip Dysplasia; Foetal Exposure During Pregnancy; Small For Dates Baby	Prednisolone			S	Transplacental	Maternal Dose: 5 Mg, Qd		Novartis
	Quensyl			S	Transplacental	Maternal Dose: 200 [Mg/D]/ Varying Dosage Between 150 And 200 Mg Daily		Not Reported
	Mono-Embolex			C	Transplacental	Maternal Dose: 3000 Iu, Qd		Not Reported
	L-Thyroxin-Jod Beta			C	Transplacental	Maternal Dose: 37.5 [Mg/D] / 75 [Mg/D]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17135501	EXPEDITED (15-DAY)		OT	CA-ROCHE-2485928		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Off Label Use; Pulmonary Fibrosis; Rheumatoid Factor Positive; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actonel			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported
	Actemra	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17135808	EXPEDITED (15-DAY)		DE, LT	CA-ROCHE-2486058		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Leflunomida			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine	S	Unknown	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Marijuana	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Kineret	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17136162	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051907		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Arthropathy; Asthma; Drug Ineffective; Drug Intolerance; Fatigue; Fine Motor Skill Dysfunction; Gastric Disorder; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Inflammation; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Motor Dysfunction; Musculoskeletal Pain; Musculoskeletal Stiffness; Off Label Use; Pain; Pruritus; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Therapeutic Product Effect Decreased; Urticaria	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	640 Milligram, Ev 4 Weeks		Not Reported
	Apo-Prednisone			S		5 Milligram		Not Reported
	Arava			S		20 Milligram, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Humira			S	Subcutaneous	40 Milligram Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S		200 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Oral	15 Milligram, Weekly (Qw)		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Weekly (Qw)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	125 Milligram, Weekly (Qw)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S		1 Gram, Once Daily (Qd)		Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
	Methotrexate			S		20 Milligram, Weekly (Qw)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17136163	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019051802			Female	CAN

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

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Cimzia	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Anakinra	S		100 Milligram	Not Reported
	Apo-Leflunomide	S		20 Milligram, 1 Every 1 Hours	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Gold	S		Unk	Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine	S		200 Milligram, 2x/Day (Bid)	Not Reported
	Hydroxychloroquine	S		300 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Leflunomide	S		20 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		300 Milligram, Once Daily (Qd)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Risedronate Sodium	S		35 Milligram, Weekly (Qw)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Subcutaneous	Solution	Not Reported

Risedronate	C				Not Reported
Hydroxychloroquine Sulfate	C		300 Milligram		Not Reported
Xeljanz	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2019	17137096	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019531932		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Gout; Loss Of Personal Independence In Daily Activities; Metabolic Disorder; Middle Insomnia; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Product Use Issue; Synovitis; Weight Increased	Celebrex			S		200 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Simponi			S		50 Mg, Unk, [1 Every 2 Week(S)]		Not Reported
	Simponi			S		50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported
	Allopurinol			C		300 Mg, Unk		Not Reported
	Clomipramine			C		Unk		Not Reported
	Folic Acid			C		1 Mg, Unk, [5 Every 1 Week(S)]		Not Reported
	Pantoloc [Pantoprazole]			C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported
	Zyloprim			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	12814630	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2016038001		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; Bone Erosion;	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not	125 Mg, Unk		Not Reported

C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Pain; Pain In Extremity; Peripheral Swelling; Physical Disability; Thrombocytosis			otherwise specified)			
	Apo-Methotrexate	S	Subcutaneous	25 Mg, Unk		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Weekly (Qw)		Not Reported
	Plaquenil	S		Unk		Not Reported
	Sulfasalazine	S		Unk		Not Reported
	Naprosyn	S		500 Mg, 2x/Day (Bid)		Not Reported
	Apo-Prednisone	S		5 Mg		Not Reported
	Methotrexate	S		25 Milligram, Weekly (Qw); Fomrulation: Solution		Not Reported
	Folic Acid	C		5 Mg, 4x/Week		Not Reported
	Gabapentin	C		Unk		Not Reported
	Lovastatin	C		Unk		Not Reported
	Metoprolol	C		50 Milligram		Not Reported
	Naproxen	C		1000 Milligram, Once Daily (Qd)		Not Reported
	Pantoprazole	C		Unk		Not Reported
	Tramadol	C		Unk		Not Reported
	Vitamin D	C		Unk		Not Reported
	Rosuvastatin Calcium	C		Unk		Not Reported
	Tofacitinib	C	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Ergocalciferol	C				Not Reported
	Vitamin D3	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	12932139	EXPEDITED (15-DAY)		OT	CA-ROCHE-1851511		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Joint Swelling; Psoriatic Arthropathy;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Lyrica	S	Oral		Not Reported
	Methotrexate Sodium	S	Intra-arterial	Solution	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	00072602	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Pregabalin	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Piroxicam	C			Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	14319105	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-113865			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Abatacept			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Norvasc			S	Oral	5 Mg, Qd		Not Reported
	Norvasc			S	Oral	5 Mg, Qd		Not Reported

Methotrexate	S	Subcutaneous	25 Mg, Qwk		Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Qwk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Amlodipine Besilate	S	Oral	5.0 Mg, Qd		Not Reported
Depo-Medrol	S	Intra-articular	Unk		Not Reported
Depo-Medrol	S	Intramuscular	120 Mg, Unk		Not Reported
Depo-Medrol	S	Intra-articular	80 Milligram		Not Reported
Asacol	S	Oral	800 Mg, Tid		Not Reported
Folic Acid	C	Oral	5 Mg, Unk		Not Reported
Ferrous Gluconate	C	Oral	300 Milligram		Not Reported
Omega Allergenic Extracts	C	Intradermal	1 Dosage Form, Qd		Not Reported
Vitamin D3	C	Oral	1000 Iu, Qd		Not Reported
Tylenol	C	Oral	500 Mg, Prn		Not Reported
Bisoprolol Fumarate	C	Oral	2.5 Milligram		Not Reported
Atacand Plus	C	Oral	1 Df, Qd		Not Reported
Cholecalciferol	C	Unknown	1 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	15719213	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018-16351		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Product Use In Unapproved Indication; Renal Mass; Vomiting	Etanercept			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Naprosyn			S	Unknown	Unknown		Not Reported
	Naprosyn			S				Not Reported
	Oxycodone			S	Unknown	Unknown		Not Reported

Prednisone	S	Unknown	Unknown		Not Reported
Rituximab	S	Unknown	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported
Medroxyprogesterone Acetate	S	Unknown	Unknown		Not Reported
Leflunomide	S	Unknown	Unknown		Not Reported
Folic Acid	S	Unknown	Unknown		Not Reported
Folic Acid	S				Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
Hydroxychloroquine Sulfate	S				Not Reported
Ciclosporin	S	Unknown	Unknown		Not Reported
Ciclosporin	S				Not Reported
Azathioprine	S	Unknown	Unknown		Not Reported
Amitriptyline	S	Unknown	Unknown		Not Reported
Elavil	S	Unknown	Unknown		Not Reported
Cyclosporin	C	Unknown	Unknown		Not Reported
Depo-Provera	C	Unknown	Unknown		Not Reported
Cyclosporin A	C	Unknown	Unknown		Not Reported
Cyclosporin A	C				Not Reported
Anakinra	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	15920485	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007765			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss; Tooth Loss	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Zostavax	S	Subcutaneous		Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Desoximetasone	C	Oral		Not Reported
	Diclofenac	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported
	Xeljanz	C	Oral	20 Milligram Daily;	Not Reported
	Cortisone Acetate	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	15923905	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007299		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral	3.2143 Milligram Daily;		Barr
	Abatacept			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Actemra	C	Unknown		Not Reported
Azathioprine	C	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Minocycline	C	Unknown		Not Reported
Penicillamine	C	Unknown		Not Reported
Prednisone	C	Unknown	12 Milligram Daily;	Not Reported
Penicillamine	C	Unknown		Not Reported
Tocilizumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	15942057	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007421		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine /00072603/	S	Unknown		Not Reported
	Hydroxychloroquine /00072603/	S	Subcutaneous		Not Reported
	Mefenamic Acid	C			Not Reported
	Prednisone	C	Oral	10 Milligram Daily;	Not Reported
	Prednisone	C	Oral	6 Milligram Daily;	Not Reported
	Tylenol	C	Unknown		Not Reported
	Dequalinium Chloride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16009026	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1017455			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown	162 Milligram.		Not Reported
	Actemra			S	Subcutaneous	162 Milligram, 2 Every 1 Week .		Not Reported
	Adalimumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, 1 Every 1		Not Reported

				Week	
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram , 3 Every 1 Week .	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram , 2 Every 1 Week .	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Cyclical .	Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, 2 Every 1 Week .	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Prednisone	C	Unknown	20 Milligram Daily;	Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16050385	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020703		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16051218	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023427		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Methotrexate			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate Injection Bp			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16069928	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024282		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder;	Methotrexate			S	Oral			Barr

Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram Daily;	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
	Folic Acid	C			Not Reported
	Prednisone	C	Unknown	10 Milligram Daily;	Not Reported
	Restasis	C	Unknown		Not Reported
	Synthroid	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16073226	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021906		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Nodule; Osteoporosis; Pain; Rheumatoid Arthritis; Stress	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Celebrex			C	Unknown	400 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported
	Vitamin D /07503901/			C	Unknown	4000 Iu (International Unit) Daily;		Not Reported

	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16075928	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022589		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown	50 Milligram Daily;		Not Reported
	Lipitor			S	Unknown	40 Milligram Daily;		Not Reported
	Plaquenil			S	Oral	300 Milligram Daily;		Not Reported
	Spiriva			S	Unknown	5 Milligram Daily;		Not Reported
	Zenhale			S	Unknown	200 Microgram Daily;		Not Reported
	Zenhale			S	Unknown	400 Milligram Daily;		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Tiotropium Bromide Monohydrate			S	Unknown	5 Milligram Daily;		Not Reported
	Formoterol Fumarate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16075930	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022340		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral	.		Barr
	Actemra			S	Intravenous (not			Not Reported

			otherwise specified)		
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Hydroxychloroquine/00072603/	S	Subcutaneous		Not Reported
	Hydroxychloroquine/00072603/	S	Oral		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Neoral	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16075960	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022719		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported

Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16075973	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022730			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16079654	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022414			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16079701	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1022656		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous	Solution		Barr
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16079734	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022759			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Advil /00422701/		C	Unknown		Not Reported
	Prednisone		C	Oral	10 Milligram Daily;	Not Reported
	Prednisone		C	Oral	6 Milligram Daily;	Not Reported
	Tylenol /00020001/		C	Unknown		Not Reported
	Acetaminophen		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16081557	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022935		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Rituxan			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported

	Hydroxychloroquine	S	Oral	400 Milligram Daily;	Not Reported
	Humira	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram Daily;	Not Reported
	Actemra	S	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16081575	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024866		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Fine Motor Skill Dysfunction; Malaise; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling	Methotrexate			S	Unknown			Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Prevacid			C	Unknown	30 Milligram Daily;		Not Reported
	Folate			C	Unknown	1 Milligram Daily;		Not Reported
	Actonel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16081607	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022855		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

						Anakinra		S	Subcutaneous	Not Reported
						Enbrel		S	Subcutaneous	Not Reported
						Hydroxychloroquine		S	Unknown	Not Reported
						Imuran		S	Unknown	Not Reported
						Remicade		S	Intravenous (not otherwise specified)	Not Reported
						Rituxan		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16082735	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022799		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Tenofovir Disoproxil			C	Unknown			Not Reported

	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16082874	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022849		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Leflunomide			S	Unknown	200 Milligram Daily;		Barr
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Apo-Acetaminophen	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported
	Acetaminophen/Codeine Phosphate	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Synthroid	C		Not Reported
	Xeljanz	C	Unknown	Not Reported
	Celebrex	C		Not Reported
	Hydromorphone Hcl	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16119843	EXPEDITED (15-DAY)		HO, OT	US-MALLINCKRODT-T201804234		83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Blood Cholesterol Increased; Blood Pressure Fluctuation; Blood Pressure Increased; Cardiac Failure Congestive; Cataract; Catheterisation Cardiac; Chills; Coronary Artery Occlusion; Cough; Dementia; Diabetes Mellitus; Dizziness; Drug Ineffective; Dyspnoea; Eye Laser Surgery; Feeling Abnormal; Gait Disturbance; Glaucoma; Hypoacusis; Influenza; Myalgia; Nasopharyngitis; Nausea; Pain In Extremity; Peripheral Swelling; Pneumonia; Product Dose Omission; Proteinuria; Pruritus; Pyrexia;	Repository Corticotropin Injection			S	Subcutaneous	40 Units/0.5 Ml, 2 Times Per Week (Wednesday, Saturday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	40 Units/0.5 Ml, 2 Times Per Week (Wednesday, Saturday)		Mallinckrodt
	Repository Corticotropin Injection			S	Unknown	80 Units, Unk		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	40 Units/0.5 Ml, 2 Times Per Week (Wednesday, Saturday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	40 Units/0.5 Ml, 2 Times Per Week (Wednesday, Saturday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	40 Units/0.5 Ml, 2 Times Per Week (Wednesday, Saturday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	40 Units, Every 72 Hours		Mallinckrodt
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Rheumatoid Arthritis; Vertigo; Vomiting; Weight Decreased	Tacrolimus		S	Unknown	1 Pill In Morning And Evening	Not Reported
	Meclizine Hcl		S	Unknown	Unk	Not Reported
	Mycophenolate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	16194804	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633466-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Off Label Use; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Topicort			S	Cutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Fosamax			S	Oral			Not Reported

	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17137892	EXPEDITED (15-DAY)		OT	CA-ROCHE-1676974		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 11 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Ativan			C				Not Reported
	Benadryl [Diphenhydramine			C				Not Reported

Hydrochloride]			
Codeine	C		Not Reported
Cortisone	C		Not Reported
Dexamethasone	C		Not Reported
Dilaudid	C	Unknown	Not Reported
Enablex [Darifenacin]	C	Unknown	Not Reported
Hydromorphone	C		Not Reported
Kadian	C	Unknown	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Unknown	Not Reported
Kineret	C	Unknown	Not Reported
Lasix [Furosemide]	C		Not Reported
Loperamide	C		Not Reported
Norflex [Orphenadrine Citrate]	C		Not Reported
Omnaris	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Synthroid	C		Not Reported
Trimethoprim	C		Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C		Not Reported
Pantoprazole	C		Not Reported
Orphenadrine Citrate	C		Not Reported
Darifenacin	C		Not Reported
Rituxan	C	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17137916	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488168		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Contraindicated Product Administered; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration 7.0 Year(S)	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration 3.0 Year(S)	Not Reported
	Sulfasalazine	S	Unknown	Therapy Duration 3.0 Year(S)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138056	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489387		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Factor Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Gold			C				Not Reported

		Imuran [Azathioprine]			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138057	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489415		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Voltaren [Diclofenac]			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zostavax			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138077	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488740			Female	CAN

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

Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Mefenamic Acid	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tylenol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138114	EXPEDITED (15-DAY)		HO	CA-ROCHE-2487386		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 12.0 Month		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Rituxan			S	Unknown	184.0		Not Reported
	Codeine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 211.0 Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral	Therapy Duration: 4.0 Year	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown	Therapy Duration: 9.0 Month	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown	Therapy Duration: 11.0 Month	Not Reported
	Xeljanz	C	Unknown	Therapy Duration: 11.0 Month	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138139	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489607		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Unknown	3.0 Year(S)		Not Reported
	Enbrel			S	Unknown	260.0 Day(S)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	6.0 Year(S)		Not Reported
	Remicade			S	Unknown	426.0 Day(S)		Not Reported
	Methotrexate			C	Unknown	7.0 Year(S)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138217	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2489308			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Red Blood Cell Sedimentation Rate	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Thrombosis; Urticaria	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Marijuana	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Methotrexate Sodium	S		Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138225	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489500			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138274	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489545		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported

Methotrexate	S	Parenteral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Azathioprine	C	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported
Minocycline	C	Unknown	Not Reported
Penicillamine	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Tocilizumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17138306	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1145050		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Methotrexate			S	Oral			Barr
	Methotrexate			S	Parenteral			Barr
	Leflunomide			S	Unknown			Barr
	Adalimumab			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Infliximab	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Actemra	C	Unknown		Not Reported
	Azathioprine	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Minocycline	C	Unknown		Not Reported
	Penicillamine	C	Unknown		Not Reported
	Prednisone	C	Unknown	12 Milligram Daily;	Not Reported
	Tocilizumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17139559	EXPEDITED (15-DAY)		OT	CA-ROCHE-1703176		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Peripheral Swelling; Rheumatoid Arthritis; Skin Reaction; Skin Swelling; Swelling; Therapeutic Response Decreased	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17139821	EXPEDITED (15-DAY)		OT	CA-ROCHE-2488344		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous drip			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17140568	EXPEDITED (15-DAY)		OT	NVSC2019CA063112			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Codeine Phosphate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Novartis
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			C	Unknown	20 Mg, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17140743	EXPEDITED (15-DAY)		OT	BE-PFIZER INC-2019528534		24 YR	Female	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Salmonella Test Positive	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Ceftriaxone Sodium			S				Pfizer
	Ceftriaxone Sodium			S				Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported
	Ampicillin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ampicillin			S				Not Reported
	Azathioprine			S		Unk		Not Reported
	Acyclovir [Aciclovir]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Acyclovir [Aciclovir]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17140779	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5878			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Bupropion	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17140945	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2019051801		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Treatment Failure; Unevaluable Event; Vomiting	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Apo-Leflunomide			S		20 Milligram, Once Daily (Qd)		Not Reported
	Apo-Prednisone			S		3 Milligram, Once Daily (Qd)		Not Reported
	Apo-Prednisone			S		25 Milligram, Once Daily (Qd)		Not Reported
	Arava			S		20 Milligram, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S		400 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine			S		400 Milligram, Once Daily (Qd)		Not Reported
	Indometacin			S		Unk		Not Reported
	Indomethacin [Indometacin]			S		Unk		Not Reported

Methotrexate	S		25 Milligram, Weekly (Qw)	Not Reported
Methotrexate	S	Oral	Unk Unk, Weekly (Qw)	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram, Once Daily (Qd)	Not Reported
Prednisone	S	Oral	3 Milligram, Once Daily (Qd)	Not Reported
Prednisone	S	Oral	25 Milligram, Once Daily (Qd)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Apo-Prednisone	S		50 Milligram	Not Reported
Prednisone	S		50 Milligram	Not Reported
Xeljanz	C	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
Cymbalta	C			Not Reported
Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17141360	EXPEDITED (15-DAY)		OT	UA-SA-2019SA334205		30 YR	Female	UKR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Granulomatous Lymphadenitis; Lymphadenitis; Lymphadenopathy; Off Label Use; Unintentional Use For Unapproved	Methotrexate			S	Intramuscular	Unk Unk, Qod (3 Injections)		Not Reported
	Methotrexate			S	Intramuscular	20 Mg, Qw		Not Reported
	Moxifloxacin Hydrochloride			S		400 Mg, Qd		Not Reported

Indication	Enoxaparin Sodium	S		0.4 Ml	Sanofi
	Plaquenil	S		400 Mg, Qd	Sanofi
	Sildenafil Citrate	S		60 Mg, Qd	Not Reported
	Methylprednisolone	C		64 Mg, Qd	Not Reported
	Methylprednisolone	C		32 Mg, Qd	Not Reported
	Methylprednisolone	C		Gradual Decrease In The Dose By 4 Mg/10 Days	Not Reported
	Methylprednisolone	C		16 Mg, Qd	Not Reported
	Methylprednisolone	C		32 Mg, Qd	Not Reported
	Methylprednisolone	C		Gradual Decrease In The Dose By 2 Mg/10 Days Until Complete Withdrawal	Not Reported
	Methylprednisolone	C	Intravenous drip	125 Unk	Not Reported
	Methylprednisolone	C	Oral	125 Unk	Not Reported
	Oxygen	C		Unk Unk, Qmn (2-3 L/Min)	Not Reported
	Oxygen	C		30-40% Oxygen Through An Oxygen Concentrator In Case Of Saturation Reduction Of Less Than 88%	Not Reported
	Chloroquine	C		500 Mg, Qd	Not Reported
	Pantoprazole	C		40 Mg	Not Reported
	Folic Acid	C		5 Mg, Qw	Not Reported
	Rivaroxaban	C		20 Mg, Qd	Not Reported
	Iloprost	C	Respiratory (inhalation)	2.5 Mg, 6id	Not Reported
	Dabigatran	C		300 Mg, Qd	Not Reported
	Warfarin	C		5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17141790	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1122658		19 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Tadalafil			S	Unknown			Not Reported
	Glyceryl Trinitrate			S	Unknown	Unk		Not Reported
	Aspirin /00002701/			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17141936	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5903		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2019	17141997	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5894		47 YR	Female	CAN

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

Arthralgia; Blood Pressure Increased; Drug Ineffective; Gout; Loss Of Personal Independence In Daily Activities; Metabolic Disorder; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity; Synovitis; Weight Increased	Methotrexate (Trade Name Unknown)		S	Oral		Not Reported
	Methotrexate (Trade Name Unknown)		S	Subcutaneous		Not Reported
	Celebrex		S	Unknown		Not Reported
	Simponi		S	Unknown		Not Reported
	Simponi		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Allopurinol		C	Unknown		Not Reported
	Clomipramine		C	Unknown		Not Reported
	Folic Acid		C	Unknown	5 Every 1 Week	Not Reported
	Pantoloc		C	Unknown		Not Reported
	Plaquenil		C	Unknown		Not Reported
	Zyloprim		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	11318943	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-050857		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Prescribed Underdose; Rheumatoid Arthritis; Synovitis; Vomiting	Orencia			S	Subcutaneous	150 Mg, Qwk		Bristol Myers Squibb
	Rituxan			S	Unknown	1 G, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported

Simponi	S	Unknown	50 Milligram, Qmo		Not Reported
Simponi	S	Subcutaneous	50 Unk		Not Reported
Naprosyn [Naproxen]	C	Unknown	500 Milligram, Bid		Not Reported
Naprosyn [Naproxen]	C	Unknown	50 Milligram		Not Reported
Celebrex	C	Unknown	200 Milligram		Not Reported
Hydroxychloroquine	C	Unknown	400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	12054230	NON-EXPEDITED			US-PFIZER INC-2016062022		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Nausea; Vomiting	Sulfasalazine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Trileptal			S		Unk		Not Reported
	Ultram			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	12244691	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016041934		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hospitalisation; Infection; Joint Surgery; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	S	Oral	10 Milligram	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Naproxen	C		500 Milligram, Bid	Not Reported
	Viread	C		Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	12330350	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054181		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	8 Milligram/Kilogram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Apo-Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Calcium Carbonate	C	Unknown	Unk	Not Reported
Cymbalta	C	Unknown	Unk	Not Reported
Elavil	C	Unknown	Unk	Not Reported
Hydrochlorothiazid	C		Unk	Not Reported
Imitrex	C	Unknown	Unk	Not Reported
Lyrica	C	Unknown	Unk	Not Reported
Plaquenil	C	Unknown	Unk	Not Reported
Premarin	C	Unknown	Unk	Not Reported
Tenormin	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Sumatriptan Succinate	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Amitriptyline Hydrochloride	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Amitriptyline	C	Unknown	Unk	Not Reported
Sumatriptan	C		Unk	Not Reported
Tofacitinib	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	13166337	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017014736		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein	Enbrel			S	Unknown	Unk		Amgen

Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Actemra	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Bid	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Milligram, Qwk	Not Reported
	Naproxen	C	Unknown	500 Milligram, Qd	Not Reported
	Methotrexate	C	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Lyrica	C	Oral	50 Mg Am And 100 Mg Hs	Not Reported
	Lyrica	C		Unk	Not Reported
	Plaquenil	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	13288085	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017030438		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	400 Milligram, Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

	Sulfasalazine	S	Oral	1 Gram, Qd	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	14299032	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050849		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Leukopenia; Lower Respiratory Tract Infection; Musculoskeletal Stiffness; Pain; Palpitations; Pulmonary Mass; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Weekly (Qw)		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S		20 Milligram, Once Daily (Qd)		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous, Once In Every 2 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Weekly (Qw)		Not Reported
	Rituximab			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Leflunomide			S		20 Milligram, Once Daily		Not Reported

				(Qd)	
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	C	Subcutaneous	17.5 Milligram	Not Reported
	Methotrexate	C	Subcutaneous	20 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	C	Subcutaneous	15 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Vitamin D	C			Not Reported
	Arthrotec	C			Not Reported
	Imuran	C			Not Reported
	Ergocalciferol	C		Unk	Not Reported
	Prednisone	C			Not Reported
	Sulfasalazine	C	Oral	1 Gram, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	14645752	NON-EXPEDITED			US-AMGEN-USASP2018035507		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	15377371	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018126860		59 YR	Female	CAN

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

Contraindicated Product Administered; Cough; Diabetes Mellitus; Flushing; Gastrointestinal Disorder; Headache; Hepatic Steatosis; Herpes Zoster; Hypertension; Liver Function Test Increased; Nervous System Disorder; Off Label Use; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Enbrel		S	Unknown	Unk	Amgen
	Orencia		S	Unknown	Unk	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Gadolinium		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Humira		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported
	Plaquenil		C	Unknown	Unk	Not Reported
	Sulfasalazine		C	Unknown	Unk	Not Reported
	Celebrex		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	5 Milligram, Qd	Not Reported
	Escitalopram Oxalate		C	Oral	10 Milligram, Qd	Not Reported
	Pantoprazole Magnesium		C	Oral	40 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	15728344	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-902500		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Hyperprolactinaemia; Myopathy; Orthostatic Hypotension	Risedronate Sodium Unk			S	Unknown			Teva
	Prednisolone			S	Unknown	7.5 Milligram Daily;		Actavis
	Domperidone Maleate			S	Unknown	30 Milligram Daily;		Not Reported
	Levothyroxine Sodium			S	Unknown	75 Microgram Daily;		Not Reported
	Carbocisteine			S	Unknown	1500 Milligram Daily;		Not Reported
	Itraconazole			S	Oral	100 Milligram Daily;		Not Reported
	Lansoprazole			S	Unknown	30 Milligram Daily;		Teva
	Uniphyllin			S	Unknown	400 Milligram Daily;		Not Reported
	Lipase;Amylase;Protease			S	Unknown	30 Milligram Daily;		Not Reported
	Iviglob-Ex			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	200 Milligram Daily;		Not Reported
	Creon	C	Unknown			Not Reported
	Propranolol	C	Unknown			Not Reported
	Theophylline	C	Unknown			Not Reported
	Pancreatin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	15801165	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	15920482	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007268			Female	CAN

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

Breast Cancer; Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Methotrexate		S	Subcutaneous	Barr
	Arava		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate Injection Bp		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	15929030	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007662			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	15942258	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1010018			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	2 Milligram Daily;		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	15946512	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1008103		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contraindication To Medical Treatment; Drug Ineffective; Hypersensitivity; Ovarian Disorder; Ovarian Operation; Pulmonary Toxicity; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16000476	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016059		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16003920	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-TEVA-2019-CA-1017774		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Minocycline			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis

Use Issue; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Oxycodone	S	Unknown		Actavis
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ilaris Single-Use Vial	S	Unknown		Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous		Not Reported
	Ilaris Single-Use Vial	S	Intravenous (not otherwise specified)		Not Reported
	Ilaris Single-Use Vial	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Unknown		Not Reported

Remicade	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sodium Aurothiomalate	S	Parenteral		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported
Gold	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Marijuana	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab	S			Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Oxyquinoline Sulfate	S	Unknown		Not Reported
Oxyquinoline Sulfate	S			Not Reported
Rituximab/Urelumab	C	Unknown		Not Reported
Kineret	C	Unknown		Not Reported
Lyrica	C	Oral		Not Reported
Lyrica	C			Not Reported
Prednisone	C	Unknown	7 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16045388	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020693		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Underdose	Methotrexate			S	Subcutaneous			Barr
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Naprosyn			S	Unknown	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16054827	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020353			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hip Surgery; Knee Arthroplasty; Osteoarthritis; Rheumatoid Arthritis; Sciatica; Unevaluable Event	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16060788	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024060			Female	CAN

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

Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate		S	Oral		Barr
	Arava		S	Unknown	20 Milligram Daily;	Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown	400 Milligram Daily;	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16075847	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022465		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Other			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16081495	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022795		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Aggression; Alopecia; Anxiety; Arthralgia; Asthenia; Blood Creatinine Increased; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder; Malaise; Peripheral Swelling; Productive Cough; Retinopathy; Secretion Discharge; Sinus Disorder; Sinusitis; Synovitis; Tachyphylaxis; Urinary Tract Infection	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prolia Pre-Filled Syringe. Preservative-Free.			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Cymbalta			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16081563	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022796		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine /00072603/	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Arava	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Prednisone	C	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16081565	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1022962		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Atenolol			C	Oral	50 Milligram Daily;		Not Reported
	Hydrochlorothiazide			C	Oral	25 Milligram Daily;		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16081601	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022996		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; No Adverse Event	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16081606	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023008		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C				Not Reported
	Darifenacin			C				Not Reported
	Desoximetasone			C				Not Reported
	Dilaudid			C				Not Reported
	Diphenhydramine			C				Not Reported
	Loperamide			C				Not Reported
	Norflex			C				Not Reported
	Omnaris			C				Not Reported
	Pantoprazole Sodium Anhydrous			C				Not Reported
	Plantago Ovata			C				Not Reported
	Synthroid			C				Not Reported
	Vagifem			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16170322	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035598		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anxiety; Asthenia; Contraindicated Product Administered; Depression; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue;	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira (Adalimumab)			S	Unknown			Not Reported
	Humira (Adalimumab)			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Hydroxychloroquine		S	Unknown		Not Reported
	Infliximab		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported
	Xeljanz		S	Unknown	10 Milligram Daily;	Not Reported
	Prednisone		S	Unknown		Not Reported
	Apo-Prednisone		S	Unknown		Not Reported
	Apo-Prednisone		S	Unknown		Not Reported
	Actemra		S	Unknown		Not Reported
	Reactine		C		10 Milligram Daily;	Not Reported
	Gabapentin		C	Unknown	1800 Milligram Daily;	Not Reported
	Acetaminophen		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16188894	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035621		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira (Adalimumab)			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Plaquenil			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Enbrel	S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Infliximab	S	Unknown			Not Reported
	Desoximetasone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16658095	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1085372			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Injection Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Abatacept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab Gp2013			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab Gp2013			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Vascular Access Complication; White Blood Cell Count Increased	Tocilizumab		S	Unknown	Not Reported
	Tocilizumab		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16662553	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1085347			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Urosepsis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16693697	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089234			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Off Label Use; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported

	Infliximab		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16694530	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1089229			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16827163	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2699437-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Device Issue; Discomfort; Gait Disturbance; Implantable Defibrillator Insertion; Joint Stiffness; Joint Swelling; Kidney Infection;	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

Musculoskeletal Stiffness; Nasopharyngitis; Oral Mucosal Blistering; Pain; Pain In Extremity; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Peripheral Swelling; Pruritus; Retinal Detachment; Sinusitis; Wrong Technique In Product Usage Process

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	16966267	NON-EXPEDITED		HO	US-PFIZER INC-2019463954		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Pneumonia Influenzal; Rash; Stomatitis	Xeljanz Xr			S	Oral	11 Mg, Daily		Pfizer
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Hydroxychloroquine			C		200 Mg, 2x/Day		Not Reported
	Forteo			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17143352	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019530525			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Lupus-Like Syndrome; Swelling Face	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Mycophenolate Sodium			S	Unknown	1 Every 12 Hour(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17144818	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149327		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fatigue; Urinary Tract Infection	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Aspirin/00002701/			C	Unknown			Not Reported
	Atenolol			C	Unknown			Not Reported
	Clopidogrel Bisulfate			C	Unknown			Not Reported
	Cyanocobalamin			C	Unknown			Not Reported
	Docusate Sodium			C	Unknown			Not Reported
	Escitalopram Oxalate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Imovane			C	Unknown			Not Reported
	Irbesartan			C	Unknown			Not Reported
	Irbesartan Hct			C	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Loratadine			C	Unknown			Not Reported
	Myrbetriq			C	Unknown			Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported
	Venlafaxine Hydrochloride			C	Unknown			Not Reported
	Vesicare			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145176	EXPEDITED (15-DAY)		OT	GB-ABBVIE-19K-167-2955604-00		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Iron Deficiency; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Humira			S	Subcutaneous			Not Reported
	Metformin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145189	EXPEDITED (15-DAY)		DE, HO	GR-ROCHE-2490974		57 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Brain Oedema; Condition Aggravated; Confusional State; Encephalitis Japanese B; Meningitis Bacterial; Speech Disorder	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145591	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1150008		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Methotrexate			S	Unknown	Solution		Barr
	Celebrex			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Imuran	S	Unknown	Not Reported
	Neoral	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145593	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1149257			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Dysstasia; Fine Motor Skill Dysfunction; Oral Herpes; Pain In Extremity; Rheumatoid Nodule; Skin Papilloma	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	2 Dosage Forms Daily;		Not Reported
	Myochrysine			S	Unknown	Solution Intramuscular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145597	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1149234			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet	Leflunomide			S	Unknown			Barr
	Methotrexate			S				Barr
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab Gp2013			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Humira (Adalimumab)			S	Subcutaneous			Not Reported
	Humira (Adalimumab)			S	Subcutaneous			Not Reported

Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Etanercept		S	Subcutaneous	Not Reported
	Actemra		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Abatacept		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145602	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149256			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	Solution		Barr
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145665	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2019051830			Female	CAN

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

Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Cimzia	S	Subcutaneous		Not Reported
	Acetaminophen	S		325 Milligram	Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride	S			Not Reported
	Actemra	S			Not Reported
	Doxycycline	S		100 Milligram, 2x/Day (Bid)	Not Reported
	Enbrel	S		40 Milligram, Weekly (Qw)	Not Reported
	Enbrel	S		50 Milligram, Weekly (Qw)	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram	Not Reported
	Leflunomide	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine	S		200 Milligram, 2x/Day (Bid)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram; Powder For Solution	Not Reported
	Hydroxychloroquine Sulfate	S		200 Milligram, 2x/Day (Bid)	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	200 Milligram, 2x/Day (Bid)	Not Reported
	Orencia	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Apo-Acetaminophen	S			Not Reported
	Tylenol A	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S		20 Milligram, Once Daily (Qd)	Not Reported
	Arava	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Celebrex	C			Not Reported
	Celecoxib	C			Not Reported
	Acetaminophen And Codeine Phosphate	C			Not Reported

	Hydromorphone Hydrochloride	C	Not Reported
	Meloxicam	C	Not Reported
	Methotrexate	C	Not Reported
	Synthroid	C	Not Reported
	Tylenol W/Codeine No. 3	C	Not Reported
	Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145674	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149247		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Condition Aggravated; Diarrhoea; Dizziness; Fall; Fatigue; Feeding Disorder; Nausea; Pain; Sensitivity To Weather Change; Tooth Fracture; Vomiting	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lorazepam			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145925	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149313			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	600 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	20 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Simponi		C	Subcutaneous		Not Reported
	Xeljanz		C	Oral	5 Milligram Daily;	Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17145969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17146458	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149253		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Large Intestine Polyp	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17146609	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019536783			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Intolerance; Foot Deformity; Inguinal Hernia; Interstitial Lung Disease; Joint Dislocation; Periarticular Disorder; Post-Traumatic Neck Syndrome; Rheumatoid Arthritis	Celebrex			S	Unknown	200 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	1500 Mg, 2x/Day		Pfizer
	Calcium Carbonate			S	Oral	3 Df, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	15 Mg, 1x/Day		Not Reported
	Relafen			S	Unknown	Unk		Not Reported
	Magnesium Aspartate			C	Oral	3 Df, 1x/Day		Not Reported
	Omega 3 [Fish Oil]			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17146691	EXPEDITED (15-DAY)		CA, OT	DE-MYLANLABS-2019M1122117		1 DAY	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Choroid Plexus Cyst; Foetal Exposure During Pregnancy; Ventricular Septal Defect	Azathioprine			S	Transplacental	150 [Mg/D]		Not Reported
	Quensyl			S	Transplacental	400 [Mg/D]		Mylan
	Calcium			C	Transplacental	Unk		Mylan
	Vomex A			C	Transplacental	150 [Mg/D (Bis 50)]		Mylan
	Influvac Tetra			C	Transplacental	Unk		Mylan
	Folsan			C	Transplacental	Unk		Mylan
	Buprenorphine			C	Transplacental	Unk		Mylan
	Budenofalk			C	Transplacental	6 [Mg/D]		Mylan
	Vitamin D Nos			C	Transplacental	2000 [Ie/D]		Mylan
	Prednisolon /00016201/			C	Transplacental	10 [Mg/D (Bis 3.5)]		Mylan

Sumatriptan	C	Transplacental	100mg/D/3 Times 6th,9th Week		Mylan
Ass	C	Transplacental	150 [Mg/D]		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17146799	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149251			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Synovitis; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17146823	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149254		33 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Seborrhoeic Dermatitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17146911	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191214737			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17147280	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191210823			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia;	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported

Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17147310	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149249		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Eye Disorder; General Physical Health Deterioration; Gluten Sensitivity	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquinesulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17147626	EXPEDITED (15-DAY)		HO	CA-ROCHE-2489623		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Subcutaneous			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17147630	EXPEDITED (15-DAY)		HO	CA-ROCHE-2487177		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration 153.0		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported

Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Therapy Duration 211.0 Day(S)	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral	Therapy Duration 4.0 Year(S)	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Orencia	S	Unknown	Therapy Duration 366.0	Not Reported
	Remicade	S	Intravenous (not	Therapy Duration 365.0	Not Reported

			otherwise specified)	
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Dec-2019	17151759	DIRECT		DS, LT, OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Depression; Hypoglycaemia; Impaired Driving Ability; Loss Of Personal Independence In Daily Activities; Suicidal Ideation; Syncope	Hydroxychloroquine Sulfate Tabs			S	Oral	Quantity:1 Tablet(S);	9 YR	Zydus Pharm
	Vitamin D3 25mcg 1000iu			C				Not Reported
	Align Probiotics			C				Not Reported
	Biotin 5000 Mcg			C				Not Reported
	Move Free Joint Health Type 2 Collagen			C				Not Reported
	Boron			C				Not Reported
	Ha			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	9450917	EXPEDITED (15-DAY)		OT	FR-ZYDUS-001867		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Antinuclear Antibody Positive; Bicytopenia; Dermatitis Psoriasiform; Dna Antibody; Drug Ineffective; Evans Syndrome; General Physical Health Deterioration; Hypergammaglobulinaemia; Lymphadenopathy; Pericarditis; Pyrexia; Pyrexia; Scar; Skin Lesion; Subacute	Omeprazole			S				Zydus Pharm
	Mycophenolic Acid			S				Not Reported
	Azathioprine/Azathioprine Sodium			C				Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone/Prednisone Acetate			S				Not Reported
	Methotrexate/Methotrexate Sodium			S				Not Reported

Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	11745381	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015120647		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Surgery; Swelling; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Rocuronium			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Sulfamethoxazole W/Trimethoprim			S	Unknown			Not Reported

Penicillin	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Rocuronium Bromide	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	12340399	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016056038		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Amitriptyline			S	Unknown	Unk (Tablet)		Not Reported
	Amitriptyline			S	Unknown	Unk (Capsule)		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk (Capsule)		Not Reported
	Celebrex			S	Unknown	Unk (Capsule, Hard)		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Parenteral	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

Voltaren	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Apo-Diclo	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Nifedipine	S	Unknown	Unk	Not Reported
Perphenazine And Amitriptyline Hydrochloride	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Apo-Diclofenac	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Parenteral	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
Celecoxib	S	Unknown	Unk	Not Reported
Misoprostol	S	Unknown	Unk	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported
Elavil [Allopurinol]	S	Unknown	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram 1 Every 2 Weeks	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram	Not Reported

Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	750 Milligram, Qwk	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo Celecoxib	S	Unknown	Unk	Not Reported
Apo Pregabalin	S	Unknown	Unk	Not Reported
Amitriptyline Hydrochloride;Perphenazine	S	Unknown	Unk	Not Reported
Apo-Amitriptyline	S	Unknown	Unk	Not Reported
Diclofenac Potassium	S	Unknown	Unk	Not Reported
Winpred	S	Unknown	Unk	Not Reported
Amitriptyline Hydrochloride	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Tofacitinib	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	12601635	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016096853			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 2 Times/Wk		Not Reported

Cell Count Decreased	Humira	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram	Not Reported
	Plaquenil	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Apo-Hydroxyquine	S	Oral	400 Milligram	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	13856318	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070219		16 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Crohn'S Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gait Disturbance; Intentional Product Use Issue; Joint Swelling; Off Label Use;	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Orencia			S	Oral	200 Milligram, Bid		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported

Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia	S	Subcutaneous	200 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Hydroxychloroquine Phosphate	S	Oral	400 Mg, Qd	Not Reported
	Hydroxychloroquine Phosphate	S	Oral	200 Mg, Bid	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Oral	200 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Methotrexate Sodium	S	Oral	20 Mg, Qwk	Not Reported
	Apo-Leflunomide	S	Unknown	20.0 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram	Not Reported
	Sulfasalazine	S	Oral	2 Gram, Bid	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	C	Oral	400 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
	Folic Acid	C	Oral	5 Milligram, Qd	Not Reported
	Prednisone	C	Oral		Not Reported
	Tofacitinib Citrate	C	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Oral	200 Milligram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	14182210	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017169862		62 YR	Male	CAN

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

Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Enbrel	S	Unknown	Unk	Amgen
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	14186327	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170049		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling;	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk Unk, Qd (1 Tablet Every 24 Hours)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Prednisone			S	Unknown	1 Tablet Every 24 Hours		Not Reported

Therapeutic Response Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	14222216	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017175418			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Endodontic Procedure; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tooth Infection; Weight Decreased	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400.0 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q4wk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Actonel			C	Unknown	35.0 Mg, Unk		Not Reported
	Esomeprazole Magnesium W/Naproxen			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Risedronate Sodium			C	Unknown	35 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	14233689	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP021679		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective;	Azathioprine			S	Unknown	Unk		Not Reported

Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Mycophenolate	S	Unknown	Unk	Apotex
	Gold	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tacrolimus	S	Unknown	6 Df, Qd	Not Reported
	Tacrolimus	S	Unknown	5 Df, Qd	Not Reported
	Tacrolimus	S	Unknown	Unk Unk, Qd	Not Reported
	Tacrolimus	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	Unk	Not Reported
	Cellcept /01275102/	S	Unknown	Unk	Not Reported
	Imuran /00001501/	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Prednisone	C	Oral	17 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	14384355	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-BI-00		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Antinuclear Antibody Positive; Arthralgia; Atelectasis; Bursitis; Conjunctivitis; Contraindicated Product Administered; Crepitations; Cushingoid; Drug Ineffective; Dry Eye; Dry Mouth; Dyspnoea;	Mobicox			S	Oral			Boehringer Ingelheim
	Alendronic Acid			S	Oral			Not Reported
	Amitriptyline [Amitriptyline Hydrochloride]			S	Oral			Not Reported
	Azathioprine			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Depo-Medrol			S	Intra-articular	Suspension Intra-Articular		Not Reported

Erythema; Eye Irritation; Eye Pain; Feeling Jittery; Fibromyalgia; Flank Pain; Haemoglobin Decreased; Impaired Work Ability; Infection; Interstitial Lung Disease; Joint Effusion; Joint Swelling; Lung Disorder; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neoplasm Malignant; Nodule; Ocular Hyperaemia; Pain; Pain In Extremity; Peripheral Swelling; Photophobia; Pleuritic Pain; Pneumonia; Pruritus; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis; Rheumatoid Nodule; Scleritis; Swelling Face; Synovial Cyst; Synovial Fluid Analysis; Tenderness; Tenosynovitis Stenosans; Therapeutic Product Effect Decreased; Thrombosis; Ulcer; Visual Impairment; Wheezing	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Dosage Form - Solution For Injection	Not Reported
	Lyrica	S	Oral		Not Reported
	Lyrica	S	Oral		Not Reported
	Methotrexate [Methotrexate Sodium]	S	Oral		Not Reported
	Methotrexate [Methotrexate Sodium]	S	Subcutaneous		Not Reported
	Naproxen Sodium	S	Oral		Not Reported
	Naproxen Sodium	S	Oral		Not Reported
	Naproxen Sodium	S	Oral		Not Reported
	Naproxen Sodium	S	Oral		Not Reported
	Pantoloc [Pantoprazole]	S	Oral	Form Of Administration - Tablet (Enteric-Coated)	Not Reported
	Pantoloc [Pantoprazole]	S	Oral	Prolonged-Release Tablet	Not Reported
	Ratio-Oxycocet	S	Unknown		Not Reported
	Septra	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Alendronate	S	Unknown		Not Reported
	Apo Amitriptyline	S	Oral		Not Reported
	Apo-Alendronate	S	Unknown		Not Reported
	Apo-Meloxicam	S	Unknown		Not Reported
	Apo-Naproxen	S	Oral		Not Reported
	Apo-Naproxen	S	Oral		Not Reported
	Apo-Naproxen	S	Oral		Not Reported
	Apo-Naproxen	S	Oral		Not Reported

Ranitidine	S	Oral	Not Reported
Ranitidine	S	Oral	Not Reported
Ranitidine	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Bactrim	S	Unknown	Not Reported
Hydroxychloroquine Phosphate	S	Unknown	Not Reported
Imuran [Azathioprine]	S	Unknown	Not Reported
Imuran [Azathioprine]	S	Unknown	Not Reported
Methylprednisolone [Methylprednisolone Sodium Succinate]	S	Intra-articular	Not Reported
Oxycocet	S	Oral	Not Reported
Oxycodone Hcl	S	Unknown	Not Reported
Vimovo	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Amitriptyline Pamoate	S	Oral	Not Reported
Esomeprazole Magnesium Trihydrate	S	Oral	Not Reported
Methylprednisolone Acetate	S	Unknown	Not Reported
Alendronate Sodium	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo Ranitidine	S	Oral	Not Reported
Meloxicam	S	Unknown	Not Reported
Oxycocet	S	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Celecoxib	C	Unknown	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Not Reported
Plaquenil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	14641000	NON-EXPEDITED			US-PFIZER INC-2018108094		50 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	15630709	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105556			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	15692314	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018171978		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Methotrexate		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	15840630	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001098		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure Via Breast Milk; Maternal Exposure During Pregnancy; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	15841614	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019007342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported

Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Simponi	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	15952043	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010727		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity; Rash	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	15974567	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported

Methotrexate	S	Unknown	15 Mg, Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Simponi	C	Subcutaneous			Not Reported
Xeljanz	C	Unknown			Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Arava	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	15978383	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013841		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use	Orencia			S	Subcutaneous	150 Mg, Unk		Bristol Myers Squibb
	Celebrex			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	200 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qwk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Naprosyn [Naproxen]			S	Unknown	500 Mg, Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16057944	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020713		49 YR	Female	CAN

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

Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Surgery; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Codeine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Barr
	Penicillin		S	Unknown		Not Reported
	Sulfamethoxazole W/Trimethoprim		S	Unknown		Teva
	Actemra		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Gold		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine /00072603/		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Rocuronium		S	Unknown		Not Reported
	Sodium Aurothiomalate		S	Parenteral		Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16103785	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1026315			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine /00072603/	S	Unknown	300 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16120602	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019045059			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Enbrel			S	Unknown	Unk		Amgen
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16161277	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034988		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; No Adverse Event;	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not			Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Incomplete			otherwise specified)		
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Naproxen	C	Unknown	500 Milligram Daily;	Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Bisoprolol	C	Unknown		Not Reported
	Digoxin	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Furosemide Sodium	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Nifedipine	C	Unknown		Not Reported
	Palafer	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Toloxin /00017701/	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported
	Xarelto	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zinc Citrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16199983	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-036501			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Prescribed Underdose; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	3 Milligram, Bid		Not Reported
	Triamcinolone			S	Intra-articular			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	5 Absent, Qd		Not Reported
	Intravenous Immune Globulin			S	Intravenous (not otherwise specified)	70 Gram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram, Qwk		Not Reported
	Kineret			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Kineret			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	250 Milligram, Qd		Not Reported
	Folic Acid			C	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16393363	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019235708		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Irritable Bowel Syndrome; Off Label Use; Off Label Use	Inflectra			S	Intravenous (not otherwise specified)	400 Mg, Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Inflectra			S	Intravenous (not otherwise specified)	400 Mg, Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Inflectra			S	Intravenous (not otherwise specified)	400 Mg, Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Methotrexate Sodium			S	Unknown			Pfizer
	Lyrica			S	Unknown	150 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	1000 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Esomeprazole			C	Unknown	40 Mg, 1x/Day		Not Reported
	Lumigan Rc			C	Ophthalmic	Unk Unk, 1x/Day		Not Reported
	Nexium [Esomeprazole Sodium]			C	Unknown	Unk		Not Reported
	Suphedrine [Pseudoephedrine Hydrochloride]			C	Unknown	10 Mg, 1x/Day		Not Reported
	Trazodone			C	Unknown	200 Mg, 1x/Day		Not Reported

Tylenol [Paracetamol]	C	Unknown	Unk		Not Reported
Tylenol [Paracetamol]	C	Unknown	3000 Mg, 1x/Day		Not Reported
Valsartan	C	Unknown	Unk Unk, 1x/Day		Not Reported
Valsartan	C	Unknown	Unk		Not Reported
Wellbutrin Xl	C	Unknown	300 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16704222	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1090969		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dermatitis Acneiform; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Hypersensitivity; Joint Swelling; Leukaemia; Nausea; Pruritus; Synovitis; Unevaluable Event	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira (Adalimumab)			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate Tablets, Usp			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16820129	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-201909000464			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerulosclerosis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	2 Dosage Form, Qd (Before Breakfast), Film-Coated Tablet		Concordia
	Benlysta			S	Subcutaneous	200 Mg, Weekly (Self Injection)		Not Reported
	Tacrolimus			C		Unk		Not Reported

Actonel	C	Unk	Not Reported
Nexium	C	Unk	Not Reported
Daiphen	C	Unk	Not Reported
Nu-Lotan	C	Unk	Not Reported
Prednisolone	C	Unk	Not Reported
Prednisolone	C	Unk	Not Reported
Prograf	C	Unk	Not Reported
Magnesium Oxide	C	Unk	Not Reported
Rebamipide	C	Unk Mg	Not Reported
Fexofenadine Hydrochloride	C	Unk	Not Reported
Nerisona	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16860738	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-093623		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	365.0 Units Unspecified		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Sulfasalazine			S	Unknown	2 Gram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	16917159	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201805-001753			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctival Hyperaemia; Drug Eruption; Erythema; Erythema; Haemorrhage Subcutaneous; Lymphadenopathy;	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Freq: Unk X 1 Days		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Unk		Concordia

Malaise; Pyrexia; Toxic Skin Eruption	Prednisolone		C	30 Mg, Qd	Not Reported
	Prednisolone		C	Dose Reduction	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17069596	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201911001903			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Carpal Tunnel Syndrome; Cyst Rupture; Deep Vein Thrombosis; Fall; Ingrowing Nail; Malignant Melanoma; Malignant Melanoma In Situ; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nail Bed Bleeding; Nail Disorder; Nodule; Onychomadesis; Pain; Pain; Poor Peripheral Circulation; Post Procedural Complication; Postoperative Thrombosis; Pruritus; Rheumatoid Arthritis; Skin Discolouration; Skin Discolouration; Skin Fissures; Skin Haemorrhage; Upper Limb Fracture; Varicose Vein; Venous Operation; Visual Impairment	Hydroxychloroquine			S	Unknown	Unk Unk, Bid		Concordia
	Hydroxychloroquine			S	Unknown	Unk Unk, Qd		Concordia
	Humira 40mg/0.4ml			S	Subcutaneous	40 Mg; 1 In 2 Wk, 40mg/0.4ml		Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous	40 Mg; 1 In 2 Wk		Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous	40 Mg; 1 In 2 Wk		Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous	Unk		Not Reported
	Mobic			C		Unk		Not Reported
	Amitriptyline			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Biotin			C		Unk		Not Reported
	Vitamin B			C		Unk		Not Reported
	Vitamin D			C		Unk		Not Reported
	Fish Oil			C		Unk		Not Reported
	Plaquenil			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17109186	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1144965		43 YR	Female	CAN

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

Arthritis; Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Disability; Drug Ineffective; Fine Motor Skill Dysfunction; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Methotrexate	S	Subcutaneous	Barr
	Simponi	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17132909	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20191208226		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis;	Motrin			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Asprin			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

Vomiting	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Tramadol Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17148599	EXPEDITED (15-DAY)		OT	CA-ROCHE-2490210			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Other			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17148627	EXPEDITED (15-DAY)		OT	CA-ROCHE-2490224			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal;	Actemra			S	Unknown			Not Reported

Rheumatoid Arthritis	Arava	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Imuran [Azathioprine]	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149115	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150112			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral	10 Milligram Daily; Solution		Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149120	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150357		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eating Disorder; Eye Disorder; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Unevaluable Event; Weight Decreased	Methotrexate			S	Unknown	Solution		Barr
	Leflunomide			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149122	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150225		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

Acetylsalicylic Acid	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Hydromorphone	C	Unknown		Not Reported
Remicade	C	Intravenous (not otherwise specified)		Not Reported
Synthroid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149123	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150227			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Drug Ineffective; Mouth Ulceration; Off Label Use; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown	25 Mg		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149127	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149894			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Methotrexate			S	Oral	Solution		Barr
	Methotrexate			S	Oral			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran			S	Unknown	450 Milligram Daily;		Not Reported
	Neoral			S	Unknown	250 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Plaquenil	S	Unknown	200 Milligram Daily;		Not Reported
Sulfasalazine	S	Oral	2 Gram Daily;		Not Reported
Sulfasalazine	S	Oral	2 Gram Daily;		Not Reported
Citalopram Hydrobromide	C	Unknown			Not Reported
Citalopram Hydrobromide	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149460	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191214983			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149469	EXPEDITED (15-DAY)		OT	CA-ROCHE-2490203			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149491	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191214981			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149553	NON-EXPEDITED			NVSC2019US067721			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149554	NON-EXPEDITED			NVSC2019US067728			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149558	NON-EXPEDITED			NVSC2019US067737			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149568	NON-EXPEDITED			NVSC2019US067723			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149666	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5898			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Glyburide			C	Unknown			Not Reported
	Infliximab			C	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Mycophenolate Mofetil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149849	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191216105			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Reactine [Cetirizine			S	Unknown			Not Reported

Alopecia; Exposure During Pregnancy; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Hydrochloride] Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Fosamax	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149990	EXPEDITED (15-DAY)		OT	FR-ACCORD-165350		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Bicytopenia; Dermatitis Psoriasiform; Dna Antibody; Drug Ineffective; Evans Syndrome; General Physical Health Deterioration; Hypergammaglobulinaemia; Lymphadenopathy; Off Label Use; Pericarditis;	Methotrexate			S	Unknown			Accord
	Mycophenolic Acid			S				Accord
	Hydroxychloroquine			S				Not Reported
	Omeprazole			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Azathioprine			C				Not Reported

Pyrexia; Scar; Skin Lesion; Subacute Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17150008	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191217118			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17150034	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191215318		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17150731	EXPEDITED (15-DAY)		LT	CA-ROCHE-2488223		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Film-Coated Tablet		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Ilaris			S	Subcutaneous	Single-Use Vial		Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported

Leflunomide	S	Oral	Not Reported
Marijuana	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S		Not Reported
Oxycodone	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Lyrica	C	Unknown	Not Reported
Rituxan	C	Unknown	Not Reported
Hydroxychloroquine Sulfate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17150878	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019AMR207382			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort;	Ventolin Hfa			S	Respiratory (inhalation)	Unk Unk, Prn, (2-4 Puffs Q 4-6years)		Glaxosmithkline

Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Benlysta	S		Unk	Glaxosmithkline
	Breo Ellipta	S	Respiratory (inhalation)	Unk	Glaxosmithkline
	Colchicine	S		Unk	Glaxosmithkline
	Prednisone	S		50 Mg, Z, (Twice Week)	Not Reported
	Meloxicam	S		Unk Unk, Prn	Not Reported
	Celebrex	S		Unk Unk, Prn	Not Reported
	Estrogel	S	Topical	Unk Unk, Qd, (Apply Daily 1 Pump)	Not Reported
	Plaquenil	S		200 Mg, Bid	Not Reported
	Dexilant	S	Oral	60 Mg, Qd	Not Reported
	Rituximab	S		Unk	Not Reported
	Arava	S		Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151144	EXPEDITED (15-DAY)		HO	CA-ROCHE-2489617		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Human Immunoglobulin (Immunoglobulin Human Normal)		S	Intravenous (not otherwise specified)	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Naproxen Sodium		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Prednisone		S	Oral	Not Reported
	Prednisone		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Triamcinolone		S	Other	Not Reported
	Triamcinolone Hexacetonide		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151591	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1149854		81 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Dementia With Lewy Bodies; Fall; Hip Fracture; Movement Disorder; Parkinson'S Disease	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151592	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150037		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151603	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150049			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151635	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150338		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Lymphadenopathy; Rheumatoid Factor Positive	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Plaquenil		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151637	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1149904		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151638	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149263			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Lipitor			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151640	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149898			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151642	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150262			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported

	Hydroxychloroquine Sulfate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151643	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1149841		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Ear Pain; Facial Paralysis; Insomnia; Pain In Jaw	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151672	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150223		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Finger Deformity; Gait Disturbance; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151675	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150215			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Joint Swelling; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151680	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150238		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Benadryl /00000402/	C	Unknown	Not Reported
Naproxen Sodium	C	Unknown	Not Reported
Plaquenil /00072602/	C	Unknown	Not Reported
Reactine /00884302/	C	Unknown	Not Reported
Venlafaxine Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151719	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150249			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Off Label Use; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folinic Acid			C	Unknown			Not Reported
	Perindopril Erbumine			C	Oral	4 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151720	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150586		63 YR	Female	CAN

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

Drug Ineffective; Drug Intolerance; Treatment Failure	Leflunomide	S	Unknown		Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Oral		Barr
	Ciclosporin	S	Unknown		Ivax
	Neoral	S	Subcutaneous		Not Reported
	Neoral	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S			Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S			Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S			Not Reported
	Xeljanz Xr	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151721	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150240			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Pseudoephedrine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17152058	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1122370			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby	Prednisone			S	Transplacental	Mother Dose 5 Mg		Not Reported
	Azathioprine			S	Transplacental	Mother Dose 2 Mg/Kg		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17152208	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027154			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Infliximab Pfizer (Unknown)			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	624 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Naproxen			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Acetaminophen			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Oxyneo			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported
	Lasix [Furosemide]			C				Not Reported
	Methylprednisolone			C				Not Reported
	Naprosyn [Naproxen]			C				Not Reported
	Oxycontin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153027	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150574		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr

Methotrexate	S	Oral	Barr
Methotrexate	S	Subcutaneous	Barr
Methotrexate	S	Subcutaneous	Barr
Methotrexate	S	Oral	Barr
Sulfasalazine	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Neoral	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153167	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150124		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Infection; Intraocular Pressure	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Increased; Ovarian Neoplasm; Pain; Rash; Rheumatoid Arthritis; Weight Decreased	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153168	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150640		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153171	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150228		50 YR	Female	CAN

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

Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Methotrexate	S	Subcutaneous	Barr
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Reactine /00884302/	C	Unknown	Not Reported
	Plaquenil /00072602/	C	Unknown	Not Reported
	Naproxen Sodium	C	Unknown	Not Reported
	Cetirizine Hydrochloride	C	Unknown	Not Reported
	Benadryl /00000402/	C	Unknown	Not Reported
	Venlafaxine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153172	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150645		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Unknown			Not Reported

	Neoral	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153173	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1150610			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil/00072602/			C	Oral	400 Milligram Daily;		Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153174	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150232		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Dermatitis Allergic; Hepatotoxicity; Nasopharyngitis; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	750 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Hydrochlorothiazide/Lisinopril Dihydrate			C	Unknown			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz Xr			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153175	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150131		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Balance Disorder; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Nodule; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Parenteral			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153177	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150567		63 YR	Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Ciclosporin	S	Unknown		Ivax
	Leflunomide	S	Unknown		Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Neoral	S	Unknown		Not Reported
	Neoral	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Endocervical		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153219	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150659			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug	Methotrexate			S	Subcutaneous	15 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported

Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	1 Gram Daily;	Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153220	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150655		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153584	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150033			Female	CAN

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

Arthralgia; Arthropathy; Drug Ineffective; Hip Arthroplasty; Hypoaesthesia; Joint Swelling; Malaise; Multiple Sclerosis; Musculoskeletal Disorder; Nausea; Vomiting	Methotrexate	S	Other		Barr
	Methotrexate	S	Oral		Barr
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Prednisone	C	Oral	15 Milligram Daily;	Not Reported
	Tylenol /00020001/	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153677	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150597		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Anakinra			S	Unknown			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153679	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150111			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Off Label Use; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Mirtazapine			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153698	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150722		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153735	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1150601			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153736	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150134			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Furuncle; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz Xr			S	Oral	11 Milligram Daily;		Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153737	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150606			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153773	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1150660		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Contraindicated Product Administered; Drug Ineffective; Hospitalisation; Meningitis	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153778	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150501		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported

Deformity; Headache; Liver Function Test Increased	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	2 Gram Daily;	Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17153782	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150662			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17154048	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150569			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17154156	NON-EXPEDITED			NVSC2019US067733			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17154586	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457093		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rosuvastatin			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17154596	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191215082			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17154597	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456781		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Prednisone			C				Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17154604	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solutiom	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17154710	NON-EXPEDITED			NVSC2019US018133		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate			S	Unknown	15 Mg (Weekly)		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Topiramate			C	Unknown	25 Mg, Qd		Not Reported
	Topiramate			C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17155002	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150603		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Deformity; Diarrhoea; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Pain; Rash; Rheumatoid Arthritis; Swelling	Methotrexate			S	Unknown			Barr
	Anakinra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17155003	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150637		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type;	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxyquinoline Sulfate			S	Unknown			Not Reported

Stress; Transplant Dysfunction; Transplant Rejection	Neoral	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Rapamune	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tacrolimus	S	Oral	6 Milligram Daily;	Not Reported
	Tacrolimus	S	Oral	4 Milligram Daily;	Not Reported
	Imuran	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17155004	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150650		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Leucovorin /00566701/			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Coversyl /00790702/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17155008	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown	2.8571 Milligram Daily;		Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17155011	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150630			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17155012	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150588			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Unknown	28.5714 Milligram Daily;		Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2019	17155149	NON-EXPEDITED			NVSC2019US017937		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Methotrexate Sodium			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Dec-2019	15668043	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018167237			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

Methotrexate	S	Oral	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	11326249	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015075697		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Joint Arthroplasty; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Cyclical		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Not Reported
	Orencia			S	Unknown	500 Milligram, Cyclical		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4mo		Not Reported
	Orencia			S	Unknown	500 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported

	Hydroxychloroquine	S	Unknown	12.5 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Q2wk	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Kineret	S	Subcutaneous	100 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	12232312	EXPEDITED (15-DAY)		CA	DE-TEVA-645985GER		1 DAY	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Septal Defect; Foetal Exposure During Pregnancy	Metoprolol			S	Transplacental	100 Milligram Daily;		Not Reported
	Lamotrigin			S	Transplacental	350 Milligram Daily;		Actavis
	Quensyl			S	Transplacental	200 Milligram Daily;		Not Reported
	Marcumar			C	Transplacental			Not Reported
	Clexane 40			C	Transplacental	80 Milligram Daily;		Not Reported
	Ass 100			C	Transplacental	100 Milligram Daily;		Not Reported
	Folsaeure			C	Transplacental	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	12356657	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016248801		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Etanercept			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	1 Df, 2x/Day		Pfizer
	Xeljanz			S	Unknown	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Xeljanz			S	Unknown	5 Mg, 2x/Day		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arthrotec			S	Unknown	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Lyrica			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Parenteral	Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Intravenous (not otherwise specified)	Unk		Unknown
	Celecoxib			S	Unknown	Unk		Pfizer
	Celecoxib			S				Pfizer
	Pregabalin			S	Unknown	Unk		Pfizer
	Naprosyn			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine			S		Unk		Not Reported

Sulfate]				
Prednisone	S	Unknown	Unk	Not Reported
Voltaren	S	Unknown	Unk	Not Reported
Amitriptyline	S	Unknown	Unk	Not Reported
Amitriptyline	S		Unk	Not Reported
Amitriptyline	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	5 Mg, Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Apo-Diclo	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Nifedipine	S	Unknown	Unk	Not Reported
Perphenazine And Amitriptyline Hydrochloride	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Apo-Amitriptyline	S	Unknown	Unk	Not Reported
Apo-Diclofenac	S	Unknown	Unk	Not Reported
Diclofenac Potassium	S	Unknown	Unk	Not Reported
Misoprostol	S	Unknown	Unk	Not Reported
Elavil [Allopurinol]	S	Unknown	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram 1 Every 2 Weeks	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	2000 Mg, Unk	Not Reported

	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	750 Milligram, Qwk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Apo-Naproxen	S			Not Reported
	Apo Celecoxib	S		Unk	Not Reported
	Apo Pregabalin	S		Unk	Not Reported
	Amitriptyline Hydrochloride/Perphenazine	S	Unknown		Not Reported
	Winpred	S		Unk	Not Reported
	Tofacitinib	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	12611441	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016366150			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue; Synovitis; White Blood Cell Count Decreased	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Humira			S	Subcutaneous	40 Milligram, Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 2 Times/Wk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	40 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Plaquenil	S	Oral	400 Milligram, Unk		Not Reported
Plaquenil	S	Oral	400 Milligram		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Unk		Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Unk		Not Reported
Apo-Hydroxyquine	S	Oral	400 Milligram, Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	400 Milligram, Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram		Not Reported
Rituximab	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	13113122	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2017001862		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Dermatitis; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug	Enbrel			S	Unknown	25 Milligram		Amgen
	Methotrexate			S	Subcutaneous	10 To 17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	10 To 12.5 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	10 To 15 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported

Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Neoplasm Skin; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Neoplasm Excision; Skin Ulcer; Therapeutic Product Effect Incomplete; Ulcer	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram, Bid	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Ciclosporin	C		150 Milligram, Qd	Not Reported
	Rituxan	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	14191119	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017489566		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

Blood Cell Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	14200416	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017491477		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk Unk, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Prednisone			S	Unknown	1 Tablet Every 24 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15563291	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016245089		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	8 Milligram/Kilogram		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Calcium Carbonate	C	Unknown	Unk	Not Reported
	Cymbalta	C	Unknown	Unk	Not Reported
	Elavil	C	Unknown	Unk	Not Reported
	Hydrochlorothiazid	C		Unk	Not Reported
	Imitrex	C	Unknown	Unk	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	Unk	Not Reported
	Tenormin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Sumatriptan Succinate	C		Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Unk	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown	Unk	Not Reported

Amitriptyline	C	Unknown	Unk		Not Reported
Sumatriptan	C		Unk		Not Reported
Tofacitinib	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15580509	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017039792		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Actemra			S	Endocervical	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, 1x/Day (Daily)		Not Reported
	Leflunomide			S		20 Mg, Daily		Not Reported
	Leflunomide			S	Unknown	10 Mg, 1x/Day		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Qwk		Not Reported
	Lyrica			C		50 Mg Am And 100 Mg Hs		Not Reported
	Methotrexate Sodium			C	Unknown	Unk		Not Reported
	Naproxen			C		500 Mg, 1x/Day		Not Reported
	Prednisone			C		Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15671134	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018494371			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer

Methotrexate Sodium	S	Oral	Unk		Pfizer
Actemra	S	Unknown	Unk		Not Reported
Arava	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15883698	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1004841			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Cortisone Acetate	S	Unknown	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15920479	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007312			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15928985	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007291		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis;	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Treatment Failure; Weight Decreased	Plaquenil		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Zostavax		S	Unknown	Not Reported
	Zostavax		S		Not Reported
	Varicella-Zoster Immune Globulin (Human)		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15930826	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007315			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Apo-Prednisone			S	Oral	3 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15934067	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007659			Male	CAN

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

Arthralgia; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Pain; Rash; Squamous Cell Carcinoma; Treatment Failure	Methotrexate	S	Unknown	Barr
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Citalopram Hydrobromide	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15939917	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1008089			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Tylenol Arthritis Pain 8 Hour			C	Unknown			Not Reported

	Gabapentin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Tylenol Arthritis	C		2600 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15942211	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007557		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Neck Surgery; Off Label Use; Spinal Column Injury; Surgical Failure; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15942232	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010017		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion;	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15959632	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1012212		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Rheumatoid Arthritis; Skin Reaction; Skin Swelling; Swelling	Methotrexate			S	Unknown			Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S				Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Prednisone	S	Unknown	Actavis
	Cimzia	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	15993953	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016226		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Tenderness; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Sodium Aurothiomalate Injection Bp			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Benadryl			C	Unknown			Not Reported
	Lasix			C	Unknown			Not Reported
	Enablex			C	Unknown			Not Reported
	Enablex			C	Unknown			Not Reported

Desoximetasone	C	Oral	Not Reported
Desoximetasone	C	Intramuscular	Not Reported
Desoximetasone	C	Intra-arterial	Not Reported
Ativan	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Norflex	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Pantoloc	C		Not Reported
Synthroid	C		Not Reported
Vagifem	C	Vaginal	Not Reported
Hydromorphone	C		Not Reported
Anakinra	C		Not Reported
Codeine	C		Not Reported
Kenalog	C		Not Reported
Kadian	C		Not Reported
Oxyneo	C		Not Reported
Pantoloc	C		Not Reported
Restasis	C		Not Reported
Trimethoprim	C		Not Reported
Urispas	C		Not Reported
Acetaminophen	C		Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Not Reported
Leflunomide	C		Not Reported
Orencia	C	Intravenous (not otherwise specified)	Not Reported
Plantago Ovata	C	Unknown	Not Reported
Plantago Ovata	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16009048	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1017285		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein	Methotrexate			S	Unknown			Barr

Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Methotrexate		S	Intravenous (not otherwise specified)		Barr
	Actemra		S	Unknown		Not Reported
	Arava		S	Oral	20 Milligram Daily;	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Plaquenil		S	Oral		Not Reported
	Remicade		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16009414	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1017293			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown	12.5 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	12.5 Milligram , 1 Every 1 Week .		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Unknown	12.5 Milligram		Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Intramuscular			Barr
	Arava			S	Oral	10 Milligram , 3 Every 1 Week .		Not Reported
	Arava			S	Oral	10 Milligram .		Not Reported
	Arava			S	Oral	200 Milligram , 2 Every 1 Week .		Not Reported
	Arava			S	Oral	10 Milligram , 2 Every 1 Week .		Not Reported

	Arava	S	Oral	10 Milligram Daily;	Not Reported
	Arava	S	Oral	10 Milligram	Not Reported
	Enbrel	S	Unknown	50 Milligram , 1 Every 1 Week	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous , 40 Milligram .	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown		Not Reported
	Hydroxychloroquine /00072603/	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	1000 Milligram .	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram, , Powder For Solution Intravenous .	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Rituxan	S	Unknown	1000 Milligram, Solution Intravenous .	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16010282	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016931		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Azathioprine			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Enbrel	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S			Not Reported
Rituxan	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Imuran	S	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16050520	EXPEDITED (15-DAY)		DS, HO	CA-TEVA-2019-CA-1020848		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16156190	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034804		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Cholesterol Increased; Bone Erosion;	Methotrexate			S	Unknown			Barr

Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity; Hypertension; Joint Dislocation; Joint Stiffness; Non-Hodgkin'S Lymphoma; Osteoarthritis; Osteoporosis; Rheumatoid Arthritis; Upper Respiratory Tract Infection	Ciclosporin	S	Unknown		Actavis
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Apo-Minocycline	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16156201	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034301			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16156222	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034332			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine 00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intraveous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16156249	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034823		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Infection; Musculoskeletal Disorder; Rheumatoid Arthritis; Sepsis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16156314	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034439		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Rheumatoid Arthritis; Synovitis; Vomiting	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S				Barr
	Enbrel			S	Subcutaneous	50milligram		Not Reported
	Enbrel			S				Not Reported
	Orencia			S	Subcutaneous	150gram		Not Reported
	Orencia			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Rituxan			S				Not Reported
	Simponi			S	Subcutaneous	50milligram, Solution Subcutaneous		Not Reported
	Simponi			S				Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S	Oral	5 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400milligram		Not Reported
	Naprosyn			S	Unknown	50milligram		Not Reported
	Celebrex			C	Unknown	200milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16161247	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034827		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hip Arthroplasty; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16161263	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1034991		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Viral Infection	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16161270	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034970			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16161272	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035389		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Varenicline Tartrate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen/Oxycodone Hydrochloride			C	Oral			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Oral	1000 Milligram Daily;		Not Reported
	Naproxen			C	Oral	1000 Milligram Daily;		Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported
	Valtrex			C	Oral	2000 Milligram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16161282	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034985		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Hepatic	Methotrexate			S	Unknown			Barr

Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Oedema Peripheral; Pyrexia	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16161299	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034400			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Arthropathy; Blood Cholesterol Increased; Contraindicated Product Administered; Gastric Disorder; Granuloma; Pain In Extremity; Pruritus; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Skin Wrinkling; Spinal Osteoarthritis; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16161315	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035607		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Methotrexate			S	Unknown			Barr

	Anakinra	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Unknown	Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16405014	EXPEDITED (15-DAY)		CA, DE, OT	FR-ASTRAZENECA-2019SE83158			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Growth Restriction; Low Birth Weight Baby; Maternal Exposure During Pregnancy; Patent Ductus Arteriosus; Premature Baby; Premature Separation Of Placenta; Right-To-Left Cardiac Shunt	Esomeprazole			S	Transplacental			Astrazeneca
	Esomeprazole			S	Transplacental			Astrazeneca
	Plaquenil			S	Transplacental			Not Reported
	Plaquenil			S	Transplacental			Not Reported
	Diffu K			S	Transplacental			Not Reported
	Diffu K			S	Transplacental			Not Reported
	Cortancyl			S	Transplacental			Not Reported
	Cortancyl			S	Transplacental			Not Reported
	Imurel			S	Transplacental			Not Reported
	Imurel			S	Transplacental			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16608051	EXPEDITED (15-DAY)		CA, DE, OT	FR-AUROBINDO-AUR-APL-2019-042768			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital	Esomeprazole			S	Transplacental	20 Milligram, Once A Day		Aurobindo

Osteodystrophy; Foetal Growth Restriction; Low Birth Weight Baby; Maternal Exposure During Pregnancy; Patent Ductus Arteriosus; Premature Baby; Premature Separation Of Placenta; Right-To-Left Cardiac Shunt	Cortancyl	S	Transplacental	1 Dosage Form, Once A Day	Not Reported
	Plaquenil	S	Transplacental	400 Milligram, Once A Day	Not Reported
	Diffu K	S	Transplacental	1 Dosage Form, Once A Day	Not Reported
	Imurel	S	Transplacental	150 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16701250	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-216066		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Pigmented Retinopathy; Maculopathy	Hydroxychloroquine			S	Unknown	Unk		Sun
	Chloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16708395	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-199337		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Retinal Depigmentation; Retinal Toxicity; Vision Blurred	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16721927	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094587		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary	Methotrexate			S	Oral			Barr
	Morphine Sulfate			S	Unknown			Actavis

Sarcoidosis; Rheumatoid Arthritis	Arava	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16748627	EXPEDITED (15-DAY)		OT	KR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-218134		56 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Pigmented Retinopathy; Retinal Toxicity	Hydroxychloroquine			S	Unknown			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16748629	EXPEDITED (15-DAY)		OT	KR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-218133		44 YR	Unknown	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Pigmented Retinopathy; Retinal Toxicity	Hydroxychloroquine			S	Unknown			Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16763267	EXPEDITED (15-DAY)		OT	KR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-198093		55 YR	Female	KOR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Pigmented Retinopathy; Retinal	Hydroxychloroquine			S	Unknown	Unk		Sun

Toxicity

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16784508	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-201908000156			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Atrial Fibrillation; Coeliac Disease; Diarrhoea; Food Allergy; Gait Disturbance; Immobile; Injection Site Rash; Injection Site Urticaria; Peripheral Swelling; Rash; Spinal Osteoarthritis; Swelling; Urticaria	Hydroxychloroquine			S	Unknown			Concordia
	Humira			S	Subcutaneous	40 Mg, 1 In 2 Wk, 40mg/0.8ml		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	16940929	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019451116		25 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	500 Mg, For 2 Consecutive Days		Pfizer
	Methylprednisolone Sodium Succinate			S				Pfizer
	Prednisolone			S	Oral	Starting Dose Of 1 Mg/Kg Per Day		Not Reported
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17095420	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019196539		50 YR	Female	CAN

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

Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Enbrel	S	Unknown	Unk	Amgen
	Pantoprazole	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Ciprofloxacin	S	Unknown	Unk	Not Reported
	Clindamycin Hcl	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Avelox	S	Unknown	Unk	Not Reported
	Keflex [Cefalexin]	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Biaxin	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enalapril Maleate	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hctz	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Losartan Potassium	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Penicillin G [Benzylpenicillin]	S	Unknown	Unk	Not Reported
	Lopressor	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Cephalexin Monohydrate	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Cipro [Ciprofloxacin]	S	Unknown	Unk	Not Reported
	Penicillin [Benzylpenicillin]	S	Unknown	Unk	Not Reported
	Isoniazid	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported

Iron Sucrose	C	Unknown	Unk		Not Reported
Esomeprazole	C	Unknown	Unk		Not Reported
Gold	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	8.5 Milligram, Qd		Not Reported
Clindamycin	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17139304	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191212735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S	Oral			Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17149606	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191215091		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Urethral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported

Cimzia	S	Subcutaneous		Not Reported
Arava	S	Oral		Not Reported
Actemra	S	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156068	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019205807			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156093	NON-EXPEDITED			NVSC2019US016548		17 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Omalizumab			S	Unknown	Unk Ukn, Unknown		Not Reported
	Omalizumab			S				Not Reported
	Cyclosporine			S	Unknown	Unk Ukn, Unknown		Novartis
	Cyclosporine			S				Novartis
	Dapsone			S	Unknown	Unk Ukn, Unknown		Not Reported
	Dapsone			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk Ukn, Unknown		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156141	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191214733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156243	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5948			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Lupus-Like Syndrome; Swelling Face	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156249	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5939			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Intolerance; Foot Deformity; Inguinal Hernia; Interstitial Lung Disease; Joint Dislocation; Periarticular Disorder; Post-Traumatic Neck Syndrome; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Calcium Carbonate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Relafen			S	Unknown			Not Reported
	Omega 3 [Fish Oil]			C	Unknown			Not Reported
	Magnesium Aspartate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156274	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191212796		43 YR	Female	CAN

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

Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Cutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156349	EXPEDITED (15-DAY)		DE, HO	GR-ROCHE-2492148		57 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Oedema; Confusional State; Encephalitis Japanese B; Mental Impairment; Speech Disorder	Rituximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156379	EXPEDITED (15-DAY)		OT	CA-SA-2019SA341973			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Macular Degeneration; Pancreatitis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S	Unknown	200 Mg, Bid		Sanofi
	Prednisone			S	Unknown	15 Mg, Bid		Not Reported
	Methotrexate			C	Unknown	20 Mg, Qw		Not Reported
	Sulfasalazine			C	Unknown	500 Mg		Not Reported
	Sulfasalazine			C	Unknown	200 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156403	EXPEDITED (15-DAY)		OT	US-LAURUS LABS LIMITED-201900439		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy; Potentiating Drug Interaction; Vision Blurred	Hydroxychloroquine			S	Unknown	Mg/Day		Not Reported
	Docetaxel			S	Unknown			Not Reported
	Cyclophosphamide			C	Unknown			Not Reported
	Corticosteroids			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156420	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191210827			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156773	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1150842			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Methotrexate			S	Unknown	Solution		Barr
	Leflunomide			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Stelara		S	Subcutaneous	Not Reported
	Xeljanz		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156844	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20191213224		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Reactine Unspecified (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Paracetamol			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Stelara			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Arava	S	Oral	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cortisone	S	Oral	Not Reported
Cortisone Acetate	S	Oral	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Unknown	Not Reported
Desoximetasone	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Folic Acid	S	Oral	Not Reported
Folic Acid	S	Oral	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Leflunomide Sandoz	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil /00072603/	S	Oral	Not Reported
Plaquenil /00072603/	S	Unknown	Not Reported
Plaquenil /00072603/	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Subcutaneous	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Topicort /00028604/	S	Subcutaneous	Not Reported
Topicort /00028604/	S	Unknown	Not Reported
Topicort /00028604/	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S		Not Reported
Paracetamol	C	Unknown	Not Reported
Atasol /00020001/	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156860	EXPEDITED (15-DAY)		OT	GB-LUPIN PHARMACEUTICALS INC.-2019-08269		51 YR	Female	GBR

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

Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Myopathy; Orthostatic Hypotension	Levothyroxine	S	Unknown	75 Microgram, Qd	Lupin
	Hydroxychloroquine	S	Unknown	200 Mg, Qd	Lupin
	Lansoprazole	S	Intracardiac	30 Mg, Qd	Not Reported
	Carbocisteine	S	Unknown	750 Milligram, Bid (Every 12 Hour)	Not Reported
	Itraconazole	S	Oral	100 Mg, Qd	Not Reported
	Immunoglobulins Nos	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisolone Acetate	S	Unknown	7.5 Mg, Qd	Not Reported
	Amylase/Lipase/Protease	S	Unknown	10 Mg, Tid (Every 8 Hour)	Not Reported
	Domperidone Maleate	S	Unknown	10 Mg, Tid (Every 8-Hour)	Not Reported
	Uniphyllin	S	Unknown	200 Milligram, Bid	Not Reported
	Risedronate Sodium	S	Unknown	35 Milligram, Unk	Not Reported
	Creon	S	Unknown	10 Mg, Tid (Every 8 Hour)	Not Reported
	Propranolol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156874	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150738		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156924	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151092			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dizziness; Dyspnoea; Nausea; Rectal Haemorrhage	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			C	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156955	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151081			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate Tab 25mg			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17156957	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151011			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Methotrexate			S	Oral			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17158908	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019534913			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Local Reaction; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Syncope; Vomiting	Sulfasalazine			S	Unknown	Unk		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Unknown
	Codeine			S	Unknown	Unk		Not Reported
	Aclasta			S	Unknown	Unk		Not Reported

	Humira	S	Unknown	Unk	Not Reported
	Plantago Afra	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Asa	C	Unknown	81 Mg, 1x/Day	Not Reported
	Cannabis Sativa	C	Unknown	Unk Unk, 1x/Day	Not Reported
	Ergocalciferol	C	Unknown	2000 Iu, 1x/Day	Not Reported
	Folic Acid	C	Unknown	5 Mg, 1 Every 3 Week(S)	Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Lipitor	C	Unknown	10 Mg, 1x/Day	Not Reported
	Methotrexate	C	Subcutaneous	22.5 Mg, Weekly	Not Reported
	Tums [Calcium Carbonate]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17159600	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019537144			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Infliximab			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Certolizumab Pegol			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Advair			C		Unk		Not Reported
	Allopurinol			C		Unk		Not Reported
	Atrovent Hfa			C		Unk (Aerosol)		Not Reported

Codeine	C	Unk	Not Reported
Cyclobenzaprine Hydrochloride	C	Unk	Not Reported
Dilaudid	C	Unk	Not Reported
Hydromorphone Hydrochloride	C	Unk	Not Reported
Ibuprofen	C	Unk	Not Reported
Leucovorin Calcium	C	Unk	Not Reported
Nexium Mups [Esomeprazole Magnesium]	C	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unk	Not Reported
Sulfasalazine	C	Unk	Not Reported
Ventolin Hfa	C	Unk	Not Reported
Xeljanz	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17160239	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053731		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Ucb
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Prednisone			S		5 Milligram		Not Reported
	Arava			S		Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		500 Milligram		Not Reported
	Fosamax			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Ucb
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

					otherwise specified)				
			Phthalylsulfathiazole	S		Unk			Not Reported
			Plaquenil [Hydroxychloroquine Phosphate]	S		400 Milligram, Once Daily (Qd)			Not Reported
			Rituxan	S	Intravenous (not otherwise specified)				Not Reported
			Sulfasalazine	S		1 Gram, 2x/Day (Bid)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Dec-2019	17160821	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1150908			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Azathioprine			C	Subcutaneous	50 Milligram Daily;		Not Reported
	Azathioprine			C	Subcutaneous	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	12675144	NON-EXPEDITED		OT	CA-AMGEN-CANSL2015044183		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Arthralgia; Bone Erosion; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Tofacitinib Citrate			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Hydromorphone			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Remicade			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	13121648	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-		58 YR	Female	CAN

2017017327

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Dermatitis; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Neoplasm Skin; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Incomplete; Ulcer	Enbrel			S	Unknown	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	10 To 12.5 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	10 To 17.5 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	10 To 15 Millgram, Qwk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Codeine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Alendronate Sodium			S	Unknown	70 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day		Not Reported
	Tocilizumab			S	Unknown	680 Mg, Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Ciclosporin			C		150 Mg, 1x/Day		Not Reported
	Rituxan			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	13458677	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP010091			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Deafness; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Headache; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Tramadol			S	Unknown	Unk		Apotex
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Apotex
	Diclofenac			S	Unknown	Unk		Apotex
	Diclofenac			S				Apotex
	Diclofenac			S				Apotex
	Diclofenac			S				Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S				Not Reported
	Naprosyn /00256201/			S				Not Reported
	Naprosyn /00256201/			S				Not Reported
	Motrin			S	Unknown	Unk		Not Reported
	Motrin			S				Not Reported
	Motrin			S				Not Reported
	Motrin			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Enbrel	S				Not Reported
Enbrel	S				Not Reported
Enbrel	S				Not Reported
Arava	S	Unknown	Unk		Not Reported
Arava	S				Not Reported
Arava	S				Not Reported
Arava	S				Not Reported
Voltaren /00372301/	S	Unknown	Unk		Not Reported
Voltaren /00372301/	S				Not Reported
Voltaren /00372301/	S				Not Reported
Voltaren /00372301/	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	14226675	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017507862			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tooth Infection; Weight Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10.0 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400.0 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750.0 Mg, Q4wk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Actonel			C	Unknown	35.0 Mg, Unk		Not Reported
	Esomeprazole Magnesium W/Naproxen			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Risedronate Sodium			C	Unknown	35 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	14705126	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018013813			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cimzia			S	Subcutaneous	Unk		Ucb
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		1 Milligram		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine Sulfate			S		400 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S	Intra-arterial	25 Milligram, Weekly (Qw)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S		Unk		Not Reported
	Plaquenil			S		400 Mg, Once Daily (Qd)		Not Reported
	Prednisone			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S		500 Milligram		Not Reported
	Sulfasalazine			S		1 G, 2x/Day (Bid)		Not Reported

	Xeljanz	S		Unk	Not Reported
	Cortisone Acetate	S		25 Milligram	Not Reported
	Diclofenac Sodium	S		Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Tofacitinib Citrate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	14961363	NON-EXPEDITED			US-AMGEN-USASP2018072669		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Enbrel			S	Unknown	Unk		Amgen
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15233081	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015249702		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly (Qwk)		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Q2wk		Pfizer
	Methotrexate Sodium			S	Oral	12.5 Mg, Qd		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Milligram		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qd		Pfizer

Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Methotrexate Sodium	S	Subcutaneous	12.5 Mg, Unk	Unknown
	Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qd	Unknown
	Methotrexate Sodium	S	Subcutaneous	20 Milligram, Qwk	Unknown
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
	Apo-Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclic, Every 2 Weeks (Q2wk)	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	12.5 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
	Kineret	S	Subcutaneous	100 Mg, 1x/Day	Not Reported
	Leflunomide	S	Oral	20 Mg, Daily	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Anakinra	S	Subcutaneous	100 Mg, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Cyclic, Every 4 Weeks (Q4wk)	Not Reported
	Orencia	S	Unknown	500 Mg, Cyclical	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Qmo	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Milligram, Q4mo	Not Reported
	Orencia	S	Unknown	500 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported

	Apo-Hydroxyquine		S	Unknown	200 Mg, 1x/Day	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15250694	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015389147		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Pain; Peripheral Swelling; Rash; Swelling; Treatment Failure; Urticaria	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rocuronium Bromide			S	Unknown	Unk		Unknown
	Rocuronium Bromide			S	Unknown	Unk		Unknown
	Codeine			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold			S		Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Sulfamethoxazole W/Trimethoprim	S	Unknown	Unk		Not Reported
Penicillin	S	Unknown	Unk		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Prednisone	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15539790	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA-965471		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis;	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2000 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Myochrysine			S	Parenteral			Not Reported

Skin Ulcer; Therapeutic Response Decreased; Ulcer	Actemra	S	Unknown	12 Milligram Daily;	Not Reported
	Rituximab Gp2013	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
	Ciclosporin	C	Unknown	150 Milligram Daily;	Not Reported
	Prednisone	C	Unknown	120 Milligram Daily;	Not Reported
	Prednisone	C		10 Milligram Daily;	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15700579	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018504596		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15800352	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996062		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15800353	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996061		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Elavil (Amitriptyline Hydrchloride)			C	Unknown			Not Reported
	Tenormin			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Imitrex			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

Premarin	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Sumatriptan Succinate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15803209	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996350		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Joint Arthroplasty; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S				Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral	12.5 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram Daily;		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Apo-Leflunomide	S	Unknown	20 Milligram Daily;		Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Methotrexate	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15804321	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996072		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15923885	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007500		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine		S	Unknown	Not Reported
	Anakinra		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15923903	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007428		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Other			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Parenteral			Barr
	Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Oral	100 Mbq Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15929035	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007669		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive	Methotrexate			S	Unknown			Barr

Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15929277	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007482		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Arthralgia; Back Pain; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Disorder; Hand Deformity; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Apo Diazepam			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported

Lyrica	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Simponi	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Piroxicam	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15930776	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007481		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Cataract Operation; Drug Ineffective; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate			S	Unknown			Barr
	Arava			S	Oral			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

	Apo-Hydroxyquine	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15930880	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007678		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	2 Every 1 Week, 40 Milligram		Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Rho D Immune Globulin Human			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown	20 Milligram Daily;		Not Reported
	Tofacitinib			S	Subcutaneous	10 Milligram Daily;		Not Reported
	Celebrex			C	Oral	400 Milligram		Not Reported
	Ibuprofen			C	Oral			Not Reported
	Lipitor			C	Oral	1 Every 1 Week, 10 Milligram		Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15930882	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007878		50 YR	Female	CAN

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

Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Methotrexate	S	Subcutaneous	Barr
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine/00072603/	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	15934001	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1007437		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Methotrexate			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral	5 Milligram Daily;		Not Reported

	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16008844	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016891		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Leflunomide	S	Unknown		Barr
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Xeljanz	C	Oral		Not Reported
	Hydroxychloroquine	C	Oral	400 Milligram Daily;	Not Reported
	Arava	C	Oral	20 Milligram Daily;	Not Reported
	Cimzia	C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16044641	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020648		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug-Induced Liver Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown	1600 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	8 Gram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16050620	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1023445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral	200 Milligram Daily;		Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16058829	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020766		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported

	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	200 Milligram Daily;	Not Reported
	Celecoxib	C	Oral	400 Milligram Daily;	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16058872	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020861			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16063272	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020731		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Infection; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown	50 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Prevacid			C	Unknown	60 Milligram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Oral	100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16069924	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021628		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr

Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra		S	Unknown		Not Reported
	Anakinra		S	Unknown		Not Reported
	Anakinra		S			Not Reported
	Arava		S	Unknown		Not Reported
	Arava		S	Oral		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Enbrel		S			Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine /00072603/		S	Unknown		Not Reported
	Hydroxychloroquine /00072603/		S	Oral		Not Reported
	Orencia		S	Unknown		Not Reported
	Orencia		S			Not Reported
	Plaquenil		S	Unknown		Not Reported
	Plaquenil		S	Oral		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Desoximetasone		C	Oral		Not Reported
	Desoximetasone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16073261	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021935		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16075605	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1022469		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Pain; Peripheral Swelling; Therapy Non-Responder	Methotrexate			S	Oral			Barr
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg Daily;		Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Oral	400 Milligram Daily;		Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16075945	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022513		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Neuropathy Peripheral;	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported

Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Arava	S	Oral	20 Milligram Daily;	Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S			Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral	1 Gram Daily;	Not Reported
	Sulfasalazine	S	Unknown	1 Gram Daily;	Not Reported
	Apo-Leflunomide	S	Unknown	11.2 Milligram Daily;	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
	Lyrica	C	Oral		Not Reported
	Prednisone	C	Unknown	15 Milligram Daily;	Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16124814	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019134156			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product	Enbrel			S	Unknown	Unk		Pfizer

Administered; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate Sodium	S	Oral	Unk		Pfizer
	Methotrexate Sodium	S	Unknown	Unk		Pfizer
	Gold	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported
	Celebrex	C	Unknown	Unk		Not Reported
	Leflunomide	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16167656	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1035423		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Immune System Disorder; Lyme Disease	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16170323	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1034974		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal;	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Gbq Daily;		Not Reported

Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sodium Aurothiomalate Injection Bp	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Anakinra	C	Unknown	Not Reported
	Ativan	C		Not Reported
	Codeine	C		Not Reported
	Desoximetasone	C		Not Reported
	Dexamethasone	C		Not Reported
	Dilaudid	C		Not Reported
	Diphenhydramine	C		Not Reported
	Enablex	C	Unknown	Not Reported
	Hydromorphone	C		Not Reported
	Kadian	C	Unknown	Not Reported
	Kenalog	C	Intra-articular	Not Reported
	Lasix	C		Not Reported
	Loperamide	C		Not Reported
	Norflex	C		Not Reported
	Omnaris	C	Unknown	Not Reported
	Oxyneo	C	Unknown	Not Reported
	Pantoprazole Sodium Anhydrous	C		Not Reported
	Restasis	C		Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Not Reported
	Synthroid	C		Not Reported
	Trimethoprim	C	Unknown	Not Reported
	Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16170333	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035595		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug	Methotrexate			S	Unknown			Barr

Ineffective; Fibromyalgia; Hepatitis; Herpes Zoster; Myocardial Infarction; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Treatment Failure	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Cyclobenzaprine	C	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Desoximetasone	C	Unknown	5 Milligram Daily;	Not Reported
	Desoximetasone	C	Oral		Not Reported
	Prednisone Acetate	C	Unknown	5 Milligram Daily;	Not Reported
	Tylenol	C	Unknown		Not Reported
	Ativan	C	Unknown		Not Reported
	Darifenacin	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Diphenhydramine	C			Not Reported
	Loperamide	C			Not Reported
	Norflex	C	Unknown		Not Reported
	Omnaris	C	Unknown		Not Reported
	Pantoprazole Sodium Anhydrous	C			Not Reported
	Plantago Ovata	C			Not Reported
	Synthroid	C	Unknown		Not Reported
	Vagifem	C	Vaginal		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16170354	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035366		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Neck Pain	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16170367	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035488		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16170405	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035480		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Oral			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Unknown	2.8571 Milligram Daily;		Not Reported
	Meloxicam			C	Oral			Not Reported
	Xeljanz			C	Oral	100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16172728	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035462		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral	Varenicline Tartrate		Not Reported

	Acetaminophen	C	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Oxycodone Hydrochloride	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Valtrex	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16173663	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035601			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown	15 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16174239	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035729		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia;	Methotrexate			S	Subcutaneous			Barr

Nausea; Thrombosis; Treatment Failure	Actemra		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16174398	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035689		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16174660	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035744			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Malignant; Onychoclasis; Tooth Loss	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Rituxan	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Zostavax	S	Subcutaneous	Powder For Suspension Subcutaneous	Not Reported
	Leflunomide	S	Oral		Barr
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported
	Xeljanz	C	Oral	20 Milligram Daily;	Not Reported
	Cortisone Acetate	C	Subcutaneous		Not Reported
	Desoximetasone	C	Unknown	10 Milligram Daily;	Not Reported
	Desoximetasone	C	Oral	10 Milligram Daily;	Not Reported
	Desoximetasone	C		10 Milligram Daily;	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Diclofenac	C		100 Milligram Daily;	Not Reported
	Diclofenac	C		100 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16177336	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036891			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Seborrhoeic Dermatitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16178042	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036661			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Methotrexate			S	Subcutaneous	15 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16183621	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037002		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Rituximab	S	Unknown			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;		Not Reported
	Apo-Hydroxyquine	S	Unknown			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
	Rituxan	C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16188233	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037040		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C	Oral	100 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16188779	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036915		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown	40 Milligram Daily;		Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram Daily;		Not Reported
	Valsartan			C	Unknown	320 Milligram Daily;		Not Reported
	Xalatan			C	Unknown	50 Milligram Daily;		Not Reported
	Zingiber Officinale			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16188798	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036993		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16193534	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037303		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthritis; Chest Pain; Condition Aggravated; Fine Motor Skill Dysfunction; Gait Disturbance; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16193606	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036935		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16354698	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016190551		52 YR	Female	CAN

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

Abdominal Discomfort; Allergic Oedema; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Urticaria	Enbrel	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Weekly	Unknown
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Weekly	Unknown
	Rituximab	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 2x/Day	Not Reported
	Leflunomide	S	Oral	10 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S		Unk	Not Reported
	Apo-Leflunomide	S	Oral	10 Mg, Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Naproxen	C		500 Mg, 2x/Day	Not Reported
	Viread	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	16904606	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201903-000501			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Prednisolone			C		50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17105596	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1010165		42 YR	Female	CAN

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

Adverse Drug Reaction; Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Wheelchair User	Methotrexate	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17107655	EXPEDITED (15-DAY)		OT	US-INTERCEPT-PM2019002145		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Fatigue; Night Sweats; Sleep Disorder; Suicidal Ideation	Ocaliva			S	Oral	5 Mg, Qd		Intercept Pharmaceuticals
	Plaquenil			S		Unk Unk, Qd		Not Reported
	Alprazolam			C				Not Reported
	Amoxicillin			C				Not Reported
	Diclofenac			C				Not Reported
	Escitalopram			C				Not Reported
	Glimepiride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17149363	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191213587			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazol			S	Unknown			Not Reported
	Plaquenil /00072603/			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17159829	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053623		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S				Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfathalidine			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Humira			S	Subcutaneous			Ucb
	Fosamax			S				Not Reported
	Folic Acid			S				Not Reported

	Etanercept	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Cortisone Acetate	S		Not Reported
	Arava	S		Not Reported
	Apo-Prednisone	S		Not Reported
	Tocilizumab	S		Not Reported
	Diclofenac	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162070	NON-EXPEDITED			NVSC2019US069931		35 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162120	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053732			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Ucb
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S		Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Ucb
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Methotrexate	S		Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S				Not Reported
Prednisone	S				Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162515	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151012			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Joint Injury; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Pain; Urticaria	Methotrexate			S	Unknown			Barr
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Ibuprofen			C				Not Reported
	Morphine			C				Not Reported
	Pertussis Vaccine			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162517	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150977		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Actemra			S	Unknown			Not Reported

Intolerance; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Arava	S	Unknown	20 Milligram Daily;		Not Reported
	Humira	S	Subcutaneous			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162519	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053742		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Ucb
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		400 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Phthalylsulfathiazole			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

	Rituxan		S	Intravenous (not otherwise specified)	Solution	Not Reported
	Sulfasalazine		S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162522	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1153510			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162635	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1150972		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Celebrex			C	Unknown			Not Reported
	Ammonium Chloride/Guaifenesin/Sulfamethoxazole/Trimethoprim			C	Unknown			Not Reported

	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162813	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053730			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Diclofenac Sodium			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Ucb
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162930	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053759		43 YR	Female	CAN

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

Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Cetirizine Hydrochloride	S			Not Reported
	Cetirizine Hydrochloride	S			Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous	Solution	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S			Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Once Daily (Qd)	Not Reported
	Adalimumab	S	Subcutaneous		Ucb
	Fosamax	S			Not Reported
	Folic Acid	S			Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Tocilizumab	S			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17163393	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053739			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand	Cetirizine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution For Injection		Not Reported

Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Simponi	S	Subcutaneous	Solution	Not Reported
	Tocilizumab	S			Not Reported
	Desoximetasone	S	Oral		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Folic Acid	S			Not Reported
	Fosamax	S	Oral		Not Reported
	Adalimumab	S	Subcutaneous	Solution	Ucb
	Hydroxychloroquine Sulfate	S			Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
	Prednisone	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tofacitinib Citrate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17163394	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053440			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus	Cimzia			S	Subcutaneous	Solution		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported

Erythematosus; Wound	Cortisone Acetate	S	Unknown		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S			Not Reported
	Folic Acid	S			Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S			Not Reported
	Humira	S	Subcutaneous	40 Milligram Solution	Ucb
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Actemra	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17163584	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053770			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution For Injection		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S				Not Reported
	Arava			S				Not Reported

Diclofenac	S				Not Reported
Etanercept	S	Subcutaneous			Not Reported
Folic Acid	S				Not Reported
Fosamax	S				Not Reported
Humira	S	Subcutaneous	Solution		Ucb
Hydroxychloroquine Sulfate	S				Not Reported
Methotrexate	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Phthalylsulfathiazole	S				Not Reported
Prednisone	S				Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17163995	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous			Ucb
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Apo-Folic Acid			S		Unk		Not Reported
	Folic Acid			S		5 Milligram		Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Apo-Prednisone			S				Not Reported
	Arava			S	Oral			Not Reported
	Cortisone Acetate			S				Not Reported
	Cortisone Acetate			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous			Ucb

	Hydroxychloroquine Sulfate	S			Not Reported
	Methotrexate Sodium	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazol	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
	Prednisone	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17164034	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053763			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Humira			S	Subcutaneous			Ucb
	Fosamax			S				Not Reported
	Folic Acid			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S				Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17164175	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053791			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Diclofenac Sodium			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous	Solution		Ucb
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S				Not Reported
	Prednisone			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17165446	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053745			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported

Enbrel	S	Subcutaneous			Not Reported
Folic Acid	S				Not Reported
Fosamax	S				Not Reported
Humira	S	Subcutaneous			Ucb
Hydroxychloroquine Sulfate	S		Unk		Not Reported
Methotrexate	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Phthalylsulfathiazole	S				Not Reported
Prednisone	S				Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17165447	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2019053719		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor	Cimzia			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S		20 Milligram		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S		Unk		Not Reported
	Pseudoephedrine Hydrochloride			S		25 Milligram		Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Paracetamol			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Stelara			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported

Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S	Oral	5 Milligram	Not Reported
	Folic Acid	S	Oral	1 Milligram	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	40 Milligram, Once Daily (Qd)	Not Reported
	Apo Prednison	S			Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S		Unk	Not Reported
	Desoximetasone	S			Not Reported
	Diclofenac Sodium	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous	Solution For Injection	Ucb
	Hydroxychloroquine	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Hydroxychloroquine	S		400 Milligram	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported

Leflunomide Sandoz	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
Methotrexate	S		Unk	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	40 Milligram, Once Daily (Qd)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		40 Milligram, Once Daily (Qd)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
Prednisone	S			Not Reported
Prednisone	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sarilumab	S			Not Reported
Sulfasalazine	S	Oral	1 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral	1 Gram, Once Daily (Qd)	Not Reported
Sulfathalidine	S	Subcutaneous	Unk	Not Reported
Sulfathalidine	S		Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous		Not Reported
Topicort [Hydrocortisone Acetate]	S		Unk	Not Reported

	Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
	Xeljanz	S			Not Reported
	Xeljanz	S			Not Reported
	Atasol [Paracetamol]	C			Not Reported
	Salazopyrin	C			Not Reported
	Tofacitinib Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17165775	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191210540			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17165856	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151419		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C		50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17165876	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151424		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Warfarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17166303	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151423		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17166318	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151532		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17166569	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019542331			Female	CAN

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

Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Oral	10 Milligram, Qwk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	12085936	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015167344		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Tofacitinib Citrate			S	Oral	5 Mg, 2x/Day		Pfizer
	Enbrel			S	Unknown	50 Mg, Usual Dose Greater Than 3month		Pfizer
	Methotrexate Sodium			S	Unknown	Unk, Usual Dose Greater Than 3month		Pfizer
	Sulfasalazine			S	Unknown	Unk,Usual Dose Greater Than 3month		Pfizer
	Apo-Leflunomide			S	Unknown	Unk, Usual Dose Greater Than 3months		Not Reported
	Plaquenil			S	Unknown	Unk, Usual Dose Greater Than 3month		Not Reported
	Humira			S	Subcutaneous	Unk, Usual Dose Greater Than 3month		Not Reported
	Cimzia			S	Subcutaneous	Usual Dose Greater Than 3 Month		Not Reported
	Actemra			S	Unknown	Unk, Usual Dose Greater Than 3month		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Aspirin	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Cymbalta	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	13000890	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP015107			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis;	Apo-Diclofenac			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown			Apotex
	Trimethoprim/Sulfamethoxazole			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Tramadol			S	Unknown	Unk		Apotex
	Asa 81			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Apotex
	Diclofenac Sodium			S	Unknown			Apotex
	Arava			S	Oral	Unk		Not Reported
	Aspirin /00002701/			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Shoulder Arthroplasty; Vomiting; Weight Decreased	Methotrexate Sodium	S	Unknown	Unk		Not Reported
	Naprosyn /00256201/	S	Unknown	Unk		Not Reported
	Plaquenil /00072602/	S	Oral	Unk		Not Reported
	Motrin	S	Unknown	Unk		Not Reported
	Voltaren /00372301/	S	Unknown			Not Reported
	Acetylsalicylic Acid W/Clopidogrel	S	Unknown			Not Reported
	Sodium Aurothiomalate	S	Parenteral			Not Reported
	Tramadol Hydrochloride	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	13869128	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2456		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Arava	C	Unknown	Not Reported
Calcium Carbonate	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Elavil	C	Unknown	Not Reported
Hydrochlorothiazide	C	Unknown	Not Reported
Imitrex	C	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported
Premarin	C	Unknown	Not Reported
Tenormin	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Sumatriptan Succinate	C	Unknown	Not Reported
Plaquenil	C	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Amitriptyline Hydrochloride	C	Unknown	Not Reported
Hydrochlorothiazide	C	Unknown	Not Reported
Amitriptyline	C	Unknown	Not Reported
Sumatriptan	C	Unknown	Not Reported
Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	14198688	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3639		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Endocervical			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	14206887	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3739		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	15716314	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-987723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral			Teva
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mobicox			S	Oral	7.5 Milligram Daily;		Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	15799492	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-996090		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Tremor; Vomiting	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Baclofen	C	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown		Not Reported
	Estradiol	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Levaquin	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Xalatan	C	Unknown		Not Reported
	Potassium Chloride	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Oral		Not Reported
	Tenofovir Disoproxil Fumaratae	C	Unknown		Not Reported
	Tenofovir Disoproxil Fumaratae	C	Unknown		Not Reported
	Tenofovir Disoproxil Fumaratae	C	Unknown		Not Reported
	Tenofovir Disoproxil Fumaratae	C	Unknown		Not Reported
	Tenofovir Disoproxil Fumaratae	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C	Unknown		Not Reported
	Methotrexate	C	Oral		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Estrogel	C	Unknown	1.8 Percent Daily;	Not Reported

	Gravol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	15920391	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1007262		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis; Onychomycosis	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Arava			C	Oral			Not Reported
	Arava			C				Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			C				Not Reported

	Infliximab			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	15944441	EXPEDITED (15-DAY)		HO, OT	US-SA-2019SA034910		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Clopidogrel Bisulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Furosemide			S	Unknown			Sanofi
	Famotidine			S	Unknown	Unk Unk, Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk Unk, Unk		Not Reported
	Doxycycline			S	Unknown	Unk Unk, Unk		Not Reported
	Trandolapril			S	Unknown	Unk Unk, Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Nifedipine			S	Unknown	Unk Unk, Unk		Not Reported
	Loperamide			S	Unknown	Unk Unk, Unk		Not Reported
	Ambien			S	Unknown	Unk Unk, Unk		Sanofi
	Gabapentin			S	Unknown	Unk Unk, Unk		Not Reported
	Esomeprazole Magnesium			S	Unknown	Unk Unk, Unk		Not Reported
	Rosuvastatin Calcium			S	Unknown	Unk Unk, Unk		Not Reported
	Potassium			S	Unknown	Unk Unk, Unk		Not Reported
	Glyceryl Trinitrate			S	Unknown	Unk Unk, Unk		Sanofi
	Metoclopramide Hydrochloride			S		Unk Unk, Unk		Not Reported
	Trazodone Hydrochloride			S		Unk Unk, Unk		Not Reported
	Isosorbide Mononitrate			S		Unk Unk, Unk		Not Reported
	Victoza			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qod		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Humira			S				Not Reported
	Flomax [Morniflumate]			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16060843	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1024073		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Methotrexate			S	Oral			Barr
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	8 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16079637	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022603			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Cough; Diabetes Mellitus; Drug Ineffective; Flushing; Gastrointestinal Disorder; Headache; Hepatic Steatosis; Herpes Zoster; Hypertension; Liver Function Test Increased; Nervous System Disorder; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Gadolinium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Celebrex			C				Not Reported
	Escitalopram Oxalate			C	Oral	10 Milligram Daily;		Not Reported
	Humira			C				Not Reported
	Pantoprazole Magnesium			C	Oral	40 Milligram Daily;		Not Reported
	Plaquenil			C				Not Reported

	Prednisone	C	5 Milligram Daily;		Not Reported
	Sulfasalazine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16098265	EXPEDITED (15-DAY)		OT	CA-009507513-1903CAN006963		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Remeron			S	Unknown	15 Milligram		Merck
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16193459	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1036681		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Fatigue; Hand Deformity; Headache; Joint Swelling; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16408267	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1743		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Irritable Bowel Syndrome; Product Use In Unapproved Indication; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown	Duration 366.0 (Unit Not Specified)		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Lyrica			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Rituxan	S	Unknown	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Esomeprazole	C	Unknown	Not Reported
Lumigan	C	Ophthalmic	Not Reported
Nexium	C	Unknown	Not Reported
Suphedrine	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported
Tylenol Es	C	Unknown	Not Reported
Tylenol Es	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Wellbutrin Xl	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16721179	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1094727		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Drug Intolerance; Leukopenia; Retinopathy; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16733249	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2019-CA-1095473			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Prescribed Underdose; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Methotrexate			S	Subcutaneous			Barr
	Methotrexate Sodium			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	6 Milligram Daily;		Not Reported
	Apo-Triamcinolone Aq			S	Intra-articular			Not Reported
	Apo-Triamcinolone Aq			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira(Adalimumab)			S	Subcutaneous			Not Reported
	Humira(Adalimumab)			S	Unknown			Not Reported
	Immune Globulin Intravenous (Human)			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret 100mg Per Syringe Single-Use,Preservative-Free Prefilled Syrin			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Kineret 100mg Per Syringe Single-Use,Preservative-Free Prefilled Syrin			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Sulfasalazine			S	Oral	250 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral	5 Unknown Daily;		Not Reported

	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous	50 Milligram Daily;	Not Reported
	Folic Acid(Natural Factors)	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16925606	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2019-057104		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Herpes Zoster Meningitis; Lung Neoplasm Malignant	Prednisolone			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Imeth			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17088869	EXPEDITED (15-DAY)		HO	NVSC2019FR050298		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Herpes Zoster Meningitis; Lung Neoplasm Malignant	Prednisone			S	Oral	5 Mg, Qd		Novartis
	Prednisone			S	Oral	5 Mg, Qd		Novartis
	Prednisolone			S	Oral	5 Mg, Qd		Not Reported
	Plaquenil			S	Oral	2 Df, Qd		Not Reported
	Imeth			S	Subcutaneous	10 Mg, Qw		Not Reported
	Imeth			S	Subcutaneous	10 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17104025	EXPEDITED (15-DAY)		OT	GR-AUROBINDO-AUR-APL-2019-076286		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis;	Metformin			S	Unknown	Unk		Aurobindo
	Belimumab			S	Unknown	Unk		Not Reported

Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Thyroxine	S	Unknown	Unk		Not Reported
	Ramipril	S	Unknown	Unk		Not Reported
	Exemestane	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Prednisolone	S	Unknown	Unk		Not Reported
	Lansoprazole	S	Unknown	Unk		Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported
	Dicoumarol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17167363	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010072		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pulmonary Toxicity; Therapy Non-Responder; Treatment Failure	Methotrexate			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Ibuprofen			C	Oral			Not Reported
	Lipitor			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17167847	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1152238		60 YR	Male	CAN

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

Drug Intolerance; Headache; Treatment Failure; Tremor	Methotrexate	S	Oral	15 Mg, 1 Every 1 Week	Barr
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Folic Acid	C	Oral	2.5 Milligram Daily;	Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Pantoprazole	C	Oral	40 Milligram Daily;	Not Reported
	Tenofovir Disoproxil Fumarate	C	Oral		Not Reported
	Tenofovir Disoproxil Fumarate	C			Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C		7.5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17167880	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5987			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported

Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Golimumab	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Advair	C	Unknown	Not Reported
	Allopurinol	C	Unknown	Not Reported
	Atrovent Hfa	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Cyclobenzaprine Hydrochloride	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Not Reported
	Ibuprofen	C	Unknown	Not Reported
	Leucovorin Calcium	C	Unknown	Not Reported
	Nexium Mups	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Ventolin Hfa	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17168052	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1152087		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis;	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported

Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Rituxan		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17168112	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151616		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Loss Of Weight; Alopecia; Arthritis; Drug Ineffective; Hepatic Enzyme Abnormal; Myocardial Infarction; Rash	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Aspirin			C	Unknown			Not Reported
	Clopidogrel Bisulfate			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17168352	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019228928			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Exposure During Pregnancy;	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Mg		Glaxosmithkline

Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk, Solution	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Solution	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17171046	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151612		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled			S	Subcutaneous			Not Reported

Positive	Syringe					
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17171048	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151709		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rabeprazole Sodium			C				Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C		10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	17171075	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151765			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Naproxen	C	500 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	13929686	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2700		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Joint Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Apo Leflunomide	S	Oral		Not Reported
Apo Leflunomide	S	Unknown		Not Reported
Apo Leflunomide	S	Unknown		Not Reported
Humira	S	Subcutaneous	Cyclic	Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Kineret	S	Subcutaneous		Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Anakinra	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Cyclic	Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	14236360	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3847			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Endodontic Procedure; Hypoaesthesia; Impaired Work Ability; Joint Swelling; Malaise; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tooth Infection; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Esomeprazole Magnesium W/Naproxen			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15259000	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1043		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Arthritis; Treatment Failure	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfamethoxazole W/Trimethoprim	S	Unknown	Not Reported
	Penicillin	S	Unknown	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15305606	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1082		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

Advil	C	Unknown		Not Reported
Tylenol	C	Unknown		Not Reported
Mefenamic Acid	C	Unknown		Not Reported
Dequalinium Chloride	C	Unknown		Not Reported
Acetaminophen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15320258	EXPEDITED (15-DAY)		OT	CA-ROCHE-2173456		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown	Therapy Duration: 5.0 Month(S)		Not Reported
	Arava			S	Unknown	Therapy Duration: 2.0 Month(S)		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7.0 Month(S)		Not Reported
	Methotrexate Sodium			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	4.0 Month(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	7.0 Month(S)		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15708014	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3644		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15798083	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-995467		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15851412	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001570		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15860932	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0165			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15876664	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1004861		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Teva-Prednisone			S	Unknown			Actavis
	Teva-Prednisone			S	Unknown			Actavis
	Naproxen Sodium			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Subcutaneous			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Plaquenil			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	15993834	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1015401			Female	CAN

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

Arthralgia; Burning Sensation; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Oral		Barr
	Adalimumab	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Cimzia	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Barr
	Sarilumab	S	Unknown		Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram Daily;	Not Reported
	Methotrexate	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16000643	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016783		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease;	Methotrexate			S	Unknown			Barr

Nodule; Rheumatoid Arthritis; Treatment Failure	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Barr
	Naproxen	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16073209	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021788			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Gait Disturbance; Herpes Zoster; Musculoskeletal Pain; Musculoskeletal Stiffness; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tramadol			C		100 Milligram Daily;		Not Reported
	Celebrex			C				Not Reported
	Tramacet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16085248	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06871		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Anti-Cyclic	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unknown		Not Reported

Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Bone Cyst; Bone Erosion; C-Reactive Protein Abnormal; Diabetes Mellitus; Drug Ineffective; Hepatic Steatosis; Hypertension; Joint Ankylosis; Joint Swelling; Liver Disorder; Musculoskeletal Stiffness; Osteolysis; Pain; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Upper Respiratory Tract Infection	Actemra	S	Unknown	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Arava	S	Oral	Unknown	Not Reported
	Arava	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Remicade	S	Subcutaneous	Unknown, Powder For Solution Intravenous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Infliximab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16193552	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1037286		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Methotrexate		S	Unknown		Barr
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil		S	Oral	400 Milligram Daily;	Not Reported
	Plaquenil		S	Oral	400 Milligram Daily;	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Naproxen		C	Unknown		Not Reported
	Sulfasalazine		C	Unknown	3 Gram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16198911	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1038628		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)		
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S			Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Cellcept	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Celebrex	C	Unknown		Not Reported
	Prednisone	C	Unknown	7 Milligram Daily;	Not Reported
	Humira	C	Subcutaneous		Not Reported
	Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16412489	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA021776			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Irritable Bowel Syndrome; Off Label Use; Off Label Use	Inflectra			S	Intravenous (not otherwise specified)	400 Mg, Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Inflectra			S	Intravenous (not otherwise specified)	400 Mg, Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Inflectra			S	Intravenous (not otherwise specified)	400 Mg, Q (Every) 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	150 Mg, Unk		Not Reported

Sulfasalazine	S	Unknown	1000 Mg, 2x/Day	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Esomeprazole	C	Unknown	40 Mg, 1x/Day	Not Reported
Lumigan Rc	C	Ophthalmic	Unk Unk, 1x/Day	Not Reported
Nexium [Esomeprazole Sodium]	C	Unknown	Unk	Not Reported
Suphedrine [Pseudoephedrine Hydrochloride]	C	Unknown	10 Mg, 1x/Day	Not Reported
Trazodone	C	Unknown	200 Mg, 1x/Day	Not Reported
Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported
Tylenol [Paracetamol]	C	Unknown	3000 Mg, 1x/Day	Not Reported
Valsartan	C	Unknown	Unk Unk, 1x/Day	Not Reported
Valsartan	C	Unknown	Unk	Not Reported
Wellbutrin Xl	C	Unknown	300 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16679714	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1086659		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster;	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Joint Swelling; Rheumatoid Arthritis; Wheelchair User	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine/00072603/	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;	Not Reported
	Aspirin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16902053	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-041960		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Hot; Immune System Disorder; Mass; Oropharyngeal Squamous Cell Carcinoma; Pain; Pyrexia; Throat Irritation	Bosentan			S	Oral			Zydus Pharm
	Apixaban			C	Unknown			Not Reported
	Nifedipine			C	Oral			Not Reported
	Mycophenolate Mofetil			C	Oral			Not Reported
	Tacrolimus			C	Unknown	2 Mg In Morning/ 3 Mg In Evening		Not Reported
	Folic Acid			C	Oral			Not Reported

Prednisone	C	Oral			Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Atovaquone	C	Oral			Not Reported
Sildenafil	C	Oral			Not Reported
Zoledronic Acid	C	Intravenous (not otherwise specified)			Not Reported
Omeprazole	C	Oral			Not Reported
Cyanocobalamin	C	Oral			Not Reported
Acetylsalicylic Acid	C	Oral			Not Reported
Calcium Carbonate/Colecalciferol	C	Unknown	600 Mg/400 Iu		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	16932171	EXPEDITED (15-DAY)		OT	GR-ALLERGAN-1941614US			Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Prednisolone Unk			S	Unknown	Unk		Allergan
	Thyroxine			S	Oral	Unk		Not Reported
	Thyroxine			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Lansoprazole			S	Unknown	Unk		Not Reported
	Ramipril			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Dicumarol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17042327	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP024673		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Acetaminophen			S	Unknown	325 Mg, Unk		Apotex
	Acetaminophen			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Q.12h (Therapy Duration: 731 Unit Unspecified)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	2000 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk, Q.Wk.		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Tylenol /00020001/			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17117759	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1119294		41 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Skin Exfoliation	Prednisone			S	Oral	25 Milligram, Qd		Not Reported
	Kardegic			S	Oral	75 Milligram, Qd		Mylan
	Plaquenil /00072602/			S	Oral	400 Milligram, Qd, 200 Mg Matin Et Soir		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17175621	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019054444			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Solution For Infusion		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Actemra			S				Not Reported
	Apo-Prednisone			S				Not Reported
	Arava			S				Not Reported
	Cortisone Acetate			S				Not Reported
	Diclofenac			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S				Not Reported
	Humira			S	Subcutaneous	Solution For Injection		Ucb
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Prednisone			S				Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17175715	EXPEDITED (15-DAY)		OT	NVSC2019US068527			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Gait Inability; Paraesthesia	Triamcinolone Acetonide			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported
	Aquaphor			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17176380	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1153231			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Oedema; Retinopathy	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Acetaminophen			C	Unknown	2 Dosage Forms Daily;		Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Nexium [Esomeprazole Sodium]			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Vitamins Nos			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17176633	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019054450		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain;	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

Pemphigus; Swelling; Systemic Lupus Erythematosus			otherwise specified)			
	Simponi	S	Subcutaneous	Unk		Not Reported
	Actemra	S				Not Reported
	Arava	S	Oral	Unk		Not Reported
	Desoximetasone	S	Cutaneous	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Folic Acid	S		Unk		Not Reported
	Fosamax	S		Unk		Not Reported
	Humira	S	Subcutaneous	Solution		Ucb
	Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate	S		Unk		Not Reported
	Methotrexate	S		Unk		Not Reported
	Orencia	S	Subcutaneous	Unk		Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk		Not Reported
	Prednisone	S		Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17176736	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6005			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17178069	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1153174			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza; Muscle Strain; Nasopharyngitis; Nephrolithiasis; Urinary Tract Infection	Leflunomide			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Methotrexate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17178079	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2019-CA-1153489		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bone Erosion; Chills; Chronic Obstructive Pulmonary Disease; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gait Inability; Hepatic Enzyme Abnormal; Infection; Malaise; Mobility Decreased; Neuropathy Peripheral; Osteoarthritis; Pain In Extremity; Pyrexia; Rheumatoid Arthritis; Urinary Tract Infection; Urine Abnormality; Urine Odour Abnormal; Vomiting; Wheelchair User	Leflunomide			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Milligram Daily;		Not Reported
	Actonel			C	Unknown			Not Reported
	Advair			C	Unknown			Not Reported
	Ferrous Gluconate			C	Oral	300 Milligram Daily;		Not Reported
	Fish Oil			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown	25 Milligram Daily;		Not Reported
	Magnesium Sulfate			C	Unknown			Not Reported

Olmesartan Medoxomil	C	Unknown	40 Milligram Daily;	Not Reported
Omega 3 /01333901/	C	Unknown		Not Reported
Omega-3 Marine Triglycerides	C	Unknown		Not Reported
Oxybutin	C	Unknown	2.5 Milligram Daily;	Not Reported
Prednisone	C	Unknown	9 Milligram Daily;	Not Reported
Rabeprazole Sodium	C	Unknown	20 Milligram Daily;	Not Reported
Rabeprazole Sodium	C	Oral	40 Milligram Daily;	Not Reported
Spiriva	C	Unknown		Not Reported
Tiotropium Bromide	C	Unknown	72 Microgram Daily;	Not Reported
Tylenol /00020001/	C	Unknown		Not Reported
Vitamin B12 /00056201	C	Unknown	1500 Milligram Daily;	Not Reported
Vitamin C /00008001/	C	Unknown		Not Reported
Vitamin C Mse Matrix	C	Oral	1000 Milligram Daily;	Not Reported
Zinc Gluconate	C	Unknown	25 Milligram Daily;	Not Reported
Zopiclone	C	Unknown		Not Reported
Folic Acid	C	Oral	5 Milligram Daily;	Not Reported
Hydroxychloroquine	C	Oral	2 Dosage Forms Daily;	Not Reported
Senna Alexandrina	C	Oral		Not Reported
Amlodipine	C	Unknown	5 Milligram Daily;	Not Reported
Ascorbic Acid	C	Oral	1000 Milligram Daily;	Not Reported
Calcium	C	Unknown	1000 Milligram Daily;	Not Reported
Citalopram	C	Unknown	30 Milligram Daily;	Not Reported
Co-Enzyme Q10	C	Unknown		Not Reported
Copper Sulfate	C	Unknown		Not Reported
D-Alpha Tocopherol	C	Unknown		Not Reported
D-Alpha Tocopherol/Fish Oil	C	Unknown		Not Reported
Docosahexaenoic Acid	C	Unknown		Not Reported
Docusate Sodium	C	Unknown		Not Reported
Ergocalciferol	C	Unknown	3000 Dosage Forms Daily;	Not Reported

	Fatty Acids Nos	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17178084	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1153497		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Rheumatoid Arthritis; Wheelchair User	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Aspirin /00002701/			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17178944	EXPEDITED (15-DAY)		HO	US-ZYDUS-044647		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brudzinski'S Sign; Diarrhoea; Headache; Lethargy; Meningism; Mental Status Changes;	Hydroxychloroquine			S				Zydus Pharm
	Methotrexate			S				Not Reported
	Mycophenolic Acid			S				Not Reported
	Methylprednisolone			S				Not Reported

Nausea; Pyrexia; Vomiting; West Nile Viral Infection	Rituximab	S	Not Reported
	Prednisone/Prednisone Acetate	S	Not Reported
	Sulfamethoxazole/Trimethoprim	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17179077	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1153329		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Back Pain; Fall; Inflammatory Pain; Lumbar Vertebral Fracture; Pruritus; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Entocort			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methylprednisolone Acetate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17179261	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1153341		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Dyspepsia; Nodule; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17179602	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-			Female	CAN

CA2019230045

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution For Injection		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17179611	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019229873			Female	CAN

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

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17179748	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1153475		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Burning Sensation; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Unknown			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Oral		Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17179968	EXPEDITED (15-DAY)		DE, OT	CA-PFIZER INC-2019541123		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis;	Doxycycline Hyclate			S	Unknown	50 Mg, Unk		Pfizer
	Enbrel			S	Unknown	Unk, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Aurothiomalate De Sodium			S	Unknown	Unk		Not Reported

Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Aurothiomalate De Sodium	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	10 Mg, 1x/Day	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab/Urelumab	C	Unknown	Unk	Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17180880	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1153312			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Folic Acid	C	Oral	2.5 Milligram Daily;		Not Reported
Methotrexate	C	Oral			Not Reported
Pantoprazole	C				Not Reported
Pantoprazole Magnesium	C	Oral	40 Milligram Daily;		Not Reported
Tenofovir Disoproxil	C				Not Reported
Tenofovir Disoproxil Fumarate	C				Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown			Not Reported
Xeljanz	C				Not Reported
Zopiclone	C	Unknown	7.5 Milligram Daily;		Not Reported
Zopiclone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17180885	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1153512		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Mouth Ulceration; Vasculitic Rash	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous	12.5 Milligram Daily;		Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown	100 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	1 Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2019	17182156	EXPEDITED (15-DAY)		OT	NVSC2019CA073777			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk (Injection)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	11682807	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2015-09646		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Iron Deficiency; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin			S	Unknown	Unk		Aurobindo
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Once A Day		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	12696508	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1477		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Therapeutic Response Decreased; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown	Usual Dose > 3 Months		Not Reported
	Enbrel			S	Unknown	Usual Dose > 3 Months		Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Usual Dose > 3 Months		Not Reported
	Apo-Leflunomide			S	Unknown	Usual Dose > 3 Months		Not Reported
	Plaquenil			S	Unknown	Usual Dose > 3 Months		Not Reported
	Humira			S	Subcutaneous	Usual Dose > 3 Months		Not Reported
	Cimzia			S	Transmammary	Usual Dose >3 Month		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown	Usual Dose >3month		Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Xeljanz	S	Oral	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Aspirin	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Remicade	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	13132615	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0240		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Dermatitis; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral	10 To 12.5 Milligram		Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous	10 To 17.5 Milligram		Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous	10 To 15 Millgram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported

Hypercalcaemia; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities; Neoplasm Skin; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Neoplasm Excision; Skin Ulcer; Therapeutic Product Effect Incomplete; Ulcer	Humira	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Rituxan	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	14971016	NON-EXPEDITED			US-PFIZER INC-2018217549		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	15841112	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-999903			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Otezla	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Stelara	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	16043916	EXPEDITED (15-DAY)		HO	US-SA-2019SA060127		63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Arthralgia; Arthritis; Condition Aggravated; Depression; Fall; Joint Injury	Kevzara			S	Subcutaneous	200 Mg, Qow		Sanofi
	Hydroxychloroquine			S				Sanofi
	Diclofenac Sodium			C				Not Reported
	Meloxicam			C				Not Reported
	Omeprazole			C				Not Reported
	Oxybutynin Chloride			C				Not Reported
	Prednisone			C				Not Reported
	Sertraline Hcl			C				Not Reported
	Simponi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	16088781	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-DE-1008137		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr

Leflunomide	S	Unknown		Barr
Methotrexate Sodium	S	Oral	20 Mg	Barr
Methotrexate Sodium	S	Subcutaneous	20 Mg	Barr
Methotrexate Sodium	S	Oral	20 Mg	Barr
Neoral	S	Subcutaneous		Not Reported
Neoral	S	Oral		Not Reported
Neoral	S	Subcutaneous		Not Reported
Humira	S	Unknown	Solution Subcutaneous	Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Hydroxychloroquine	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Hydroxychloroquine/00072603	S	Oral	Unk	Not Reported
Hydroxychloroquine/00072603	S	Subcutaneous		Not Reported
Hydroxychloroquine/00072603	S	Subcutaneous		Not Reported
Hydroxychloroquine/00072603	S	Subcutaneous		Not Reported
Hydroxychloroquine/00072603	S	Subcutaneous		Not Reported
Hydroxychloroquine/00072603	S	Oral		Not Reported
Rituxan	S	Unknown	Solution Intravenous	Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg Powder For Solution Intravenous	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported

Orencia	S	Subcutaneous	125 Mg		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	16201203	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1038081			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	16206600	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1038750			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown	200 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	5 Milligram Daily;		Not Reported

Advil	C	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Ketorolac	C	Unknown			Not Reported
Methotrexate	C	Unknown	20milligram, 1every 1weeks		Not Reported
Naproxen	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	16206634	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1038760		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Actemra			C	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	16208604	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1038709		54 YR	Female	CAN

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

Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Leflunomide		S	Oral	20 Milligram Daily;	Barr
	Actemra		S	Unknown		Not Reported
	Adalimumab		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil		S	Oral	400 Milligram Daily;	Not Reported
	Methotrexate		C	Subcutaneous		Not Reported
	Methotrexate		C	Subcutaneous		Not Reported
	Sulfasalazine		C	Oral	1 Gram Daily;	Not Reported
	Xeljanz		C	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	16410789	EXPEDITED (15-DAY)		OT	GB-JNJFOC-20180525818		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Hyperprolactinaemia; Myopathy; Orthostatic Hypotension	Domperidone			S	Unknown			Not Reported
	Sporanox			S	Oral			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Uniphyllin			S	Unknown			Not Reported
	Creon			S	Unknown			Not Reported
	Carbocisteine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Risedronate			S	Unknown			Not Reported
	Lansoprazole			S	Unknown			Not Reported
	Propanolol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17046877	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP024680			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Acetaminophen			S	Unknown	Unk		Apotex
	Acetaminophen			S	Unknown	325 Mg, Unk		Apotex
	Apo-Acetaminophen			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Doxycycline			S	Unknown	100 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	40 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	200 Mg, Bid		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	2000 Mg, Unk		Not Reported
	Tylenol /00020001/			S	Unknown	Unk		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown	Unk		Not Reported
	Celebrex			C	Oral	200 Mg, Bid		Not Reported
	Celecoxib			C	Unknown	Unk		Not Reported
	Hydromorphone			C	Unknown	Unk		Not Reported

Meloxicam	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	25 Mg, Qd		Not Reported
Methotrexate	C	Unknown	25 Mg, Q.Wk.		Not Reported
Synthroid	C	Unknown	Unk		Not Reported
Tylenol W/Codeine No. 3	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17079726	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140518			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Exostosis; Foot Deformity; Joint Dislocation; Joint Stiffness; Osteoarthritis; Osteoporosis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Barr
	Methotrexate			S				Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Leflunomide			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sirukumab			S	Unknown			Not Reported
	Stelara			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

	Cosentyx	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17137775	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-104089		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Antinuclear Antibody Positive; Bicytopenia; Dermatitis Psoriasiform; Dna Antibody; Drug Ineffective; Evans Syndrome; General Physical Health Deterioration; Hypergammaglobulinaemia; Lymphadenopathy; Pericarditis; Pyrexia; Scar; Skin Lesion; Subacute Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus	Omeprazole			S	Unknown	Unk		Aurobindo
	Prednisone			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17147537	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018240366			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Pain;	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Qd	Not Reported
	Methotrexate	S	Intra-arterial	25 Mg, We	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Unk (Solution Subcutaneous)	Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported
	Sulfasalazine	S	Unknown	1 G, Bid	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
	Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17164060	NON-EXPEDITED			NVSC2019US067437		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lichenoid Keratosis; Product Use In	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Prednisone			S	Oral	60 Mg		Not Reported

Unapproved Indication	Infliximab	C	Unknown	Unk		Not Reported
	Tacrolimus	C	Unknown	Unk		Not Reported
	Alprazolam	C	Unknown	Unk		Not Reported
	Metprolol	C	Unknown	Unk		Not Reported
	Amlodipine	C	Unknown	Unk		Not Reported
	Mirtazapine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17181841	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-201912002892			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hospitalisation; Prescribed Underdose	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	100 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17182257	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154251			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17182260	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154364		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Encephalitis; Hypoaesthesia	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Pregabalin			C	Oral	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17183623	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1156663		60 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lung Neoplasm; Pulmonary Mass	Ajovy			S	Unknown			Teva
	Stelara			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17183683	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019545712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deep Vein Thrombosis; Diarrhoea; Rash; Skin Infection; Systemic Lupus Erythematosus; Transaminases Increased;	Sulfasalazine			S	Unknown			Pfizer
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

Treatment Failure	Orencia	S	Subcutaneous	125 Mg, Weekly	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Mg, 1x/Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	1 Every 6 Weeks	Not Reported
	Folic Acid	C	Unknown	5 Mg, 1x/Day	Not Reported
	Pariet	C	Unknown	20 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17183721	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019543836		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, 1x/Day		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17183725	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019543728			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Diabetes Mellitus; Flank Pain; Lymphoma; Neutrophil Count Increased; Splenomegaly; White Blood Cell Count Increased; White Blood Cell Disorder	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Cortisone			C	Intramuscular	Unk, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17183726	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019543699		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Product Use Issue; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Unknown
	Enbrel			S	Unknown			Pfizer
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1 Df, 1x/Day		Not Reported
	Leflunomide			S	Unknown	1 Df, 1x/Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate Sodium			S	Unknown	35 Mg, Weekly		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17183764	EXPEDITED (15-DAY)		DE	CA-DRREDDYS-USA/CAN/19/0117587		75 YR	Female	CAN

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

Chest Discomfort	Atorvastatin	S	Oral	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Flovent	S	Unknown	Not Reported
	Ipratropium Bromide/Salbutamol Sulfate	S	Unknown	Not Reported
	Lasix	S	Unknown	Not Reported
	Metformin	S	Unknown	Not Reported
	Nitrazadon	S	Oral	Not Reported
	Omeprazole Magnesium	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Salmeterol Xinafoate	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17183825	EXPEDITED (15-DAY)		HO, OT	DK-APPCO PHARMA LLC-2078051		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Pneumonia Mycoplasmal	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Azathioprine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Insulin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17184371	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019232012			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective;	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclophenac			S	Unknown	Unk		Glaxosmithkline

Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Folic Acid	S	Unknown	Unk	Glaxosmithkline
	Cortisone Acetate	S	Unknown	Unk	Glaxosmithkline
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Solution For Infusion	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk, Solution For Injection	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17184937	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154281			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Aspirin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Blood Cell Count Decreased	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Penicillin G Potassium	S	Unknown	Not Reported
	Acetaminophen/Codeine Phosphate	C	Unknown	Not Reported
	Pregabalin	C		Not Reported
	Penicillin G Procaine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17184969	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154333		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Ciclosporin			S	Unknown			Ivax
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported

Plaquenil	S	Unknown			Not Reported
Plaquenil	S	Unknown			Not Reported
Plaquenil	S	Subcutaneous			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Unknown			Not Reported
Sulfasalazine	S	Oral	5000 Milligram Daily;		Not Reported
Cimzia	C	Subcutaneous			Not Reported
Risedronate	C	Unknown			Not Reported
Xeljanz	C	Oral	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17185674	EXPEDITED (15-DAY)		LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-121402			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Indometacin			S	Unknown			Not Reported
	Methotrexate			S	Oral	Unk, Qwk		Not Reported
	Naprosyn [Naproxen Sodium]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown	Unk, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186283	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154352			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186325	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154834			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Actemra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186338	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154259		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Otezla			S	Oral	60 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186483	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154344			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Nausea; Oral Discomfort; Treatment Failure	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Humira	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Methotrexate	S	Oral			Not Reported
Orencia	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sarilumab	S	Unknown			Not Reported
Simponi	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Tocilizumab	S	Unknown			Not Reported
Tofacitinib	S	Unknown			Not Reported
Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186484	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154325			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug Hypersensitivity; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Pain; Nausea; Periarthritis; Pruritus; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Etanercept			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186485	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154235			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Leflunomide			S	Unknown			Barr

Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate		S	Unknown	Barr
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Oral	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186504	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154375			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Pancytopenia; Weight Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported
	Infliximab			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186506	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154837			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Unevaluable Event; White Blood Cell Count Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186534	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154853			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Lyrica			S	Oral	300 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186681	EXPEDITED (15-DAY)		OT	NVSC2019CA075065			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk (Powder For Solution For Injection)		Not Reported

	Simponi	S	Subcutaneous	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk (Solution)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk (Solution)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186855	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154423			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	7.1429 Milligram Daily;		Not Reported
	Humira			S	Unknown	2.8571 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral	2.5 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not			Not Reported

			otherwise specified)		
	Sulfasalazine	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186872	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1154486		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Drug Intolerance; Joint Swelling; Rheumatoid Factor Positive; X-Ray Abnormal	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Diovan			C				Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid			C				Not Reported
	Sertraline			C				Not Reported
	Valtrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17186895	NON-EXPEDITED			NVSC2019US074729			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Platelet Count Decreased	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg ((Second Dose Was Given 2 Weeks Later)		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	500 Mg, Qd (For3 Days Followed By 1 Mg/Kg		Novartis

					Daily)	
	Hydroxychloroquine		S	Unknown	200 Mg, Bid	Not Reported
	Heparin		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2019	17187244	NON-EXPEDITED			NVSC2019US074521		66 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Xolair			S	Subcutaneous	600 Mg, Q2w		Not Reported
	Cyclosporine			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2019	17188270	EXPEDITED (15-DAY)		OT	NVSC2019CA076669			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Enbrel	S	Subcutaneous	Unk		Not Reported
Fosamax	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2019	17188271	EXPEDITED (15-DAY)		OT	NVSC2019CA075047			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	12806009	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2016037867		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Arava			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	40 Milligram Solution Subcutaneous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Plaquenil			S	Oral	300 Milligram, Once Daily (Qd)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram Cyclical Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Gold			S		Unk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	300 Milligram, Once Daily		Not Reported

				(Qd)	
	Actonel	S	Oral	35 Milligram, Weekly (Qw)	Not Reported
	Xeljanz	S		Unk	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram Cyclical	Not Reported
	Hydroxychloroquine	S		300 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		Unk, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S		300 Milligram Cyclical	Not Reported
	Leflunomide	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Risedronate	S		35 Milligram, Weekly (Qw)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	13766596	EXPEDITED (15-DAY)		OT	CA-UCBSA-2015042698			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Arava			S		Unk		Not Reported
	Enbrel			S		Unk, Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Weekly (Qw)		Not Reported
	Morphine Sulfate			S		Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, 2x/Day (Bid)		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			C		Unk, 5 Mg		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	14299149	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050888		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S		20 Mg, Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Leflunomide			S		20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	7.5 Milligram		Not Reported
	Methotrexate			S		7.5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Diclofenac Sodium And Misoprostol			S		50 Milligram, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Gold			C				Not Reported
	Imuran			C				Not Reported
	Arthrotec			C		50 Mg, 2x/Day (Bid)		Not Reported
	Vitamin D3			C				Not Reported
	Ergocalciferol			C				Not Reported
	Vitamin D Nos			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	14739451	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009202			Female	CAN

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

Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Acetaminophen	S	Unknown	Unk	Apotex
	Meloxicam	S	Unknown	Unk	Apotex
	Prednisone	S	Unknown	5 Mg, Qd	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Arava	S	Unknown	200 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tylenol /00020001/	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	15619990	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556541-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Pruritus; Synovitis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	15949612	EXPEDITED (15-DAY)		HO, OT	US-VALIDUS PHARMACEUTICALS LLC-US-2019VAL000034			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Coronary Artery Occlusion; Herpes Zoster;	Furosemide			S	Unknown	Unk		Validus
	Clopidogrel Bisulfate			S	Unknown	Unk		Not Reported

Mobility Decreased; Osteoporosis; Spinal Fracture	Famotidine	S	Unknown	Unk	Not Reported
	Venlafaxine Hydrochloride	S	Unknown	Unk	Not Reported
	Doxycycline	S	Unknown	Unk	Not Reported
	Trandolapril	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Unk	Not Reported
	Nifedipine	S	Unknown	Unk	Not Reported
	Loperamide	S	Unknown	Unk	Not Reported
	Ambien	S	Unknown	Unk	Not Reported
	Gabapentin	S	Unknown	Unk	Not Reported
	Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
	Rosuvastatin Calcium	S	Unknown	Unk	Not Reported
	Potassium	S	Unknown	Unk	Not Reported
	Glyceryl Trinitrate	S	Unknown	Unk	Not Reported
	Metoclopramide Hydrochloride	S	Unknown	Unk	Not Reported
	Trazodone Hydrochloride	S	Unknown	Unk	Not Reported
	Isosorbide Mononitrate	S	Unknown	Unk	Not Reported
	Victoza	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qod	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Humira	S			Not Reported
	Flomax /00889901/	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	16365379	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-183675		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency;	Lansoprazole			S	Unknown	30 Mg, Qd		Sun
Adrenal Insufficiency; Adrenal Suppression;	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported

Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Myopathy; Orthostatic Hypotension	Lipase;Amylase;Protease Unk		S	Unknown	10 Mg, Tid	Not Reported
	Prednisolone		S	Unknown	7.5 Mg, Qd	Not Reported
	Uniphyllin		S	Unknown	200 Mg, Bid	Not Reported
	Itraconazole		S	Oral	100 Mg, Qd	Not Reported
	Levothyroxine		S	Unknown	75 Microgram, Qd	Not Reported
	Domperidone Maleate		S	Unknown	10 Mg, Tid	Not Reported
	Carbocisteine		S	Unknown	750 Milligram, 1dose/12hour (750 Mg, Bid)	Not Reported
	Risedronate Sodium		S	Unknown	35 Milligram	Not Reported
	Creon		S	Unknown	10 Milligram, 1dose/8hr (10 Mg, Tid)	Not Reported
	Ivig		S	Unknown	Unk	Not Reported
	Propanolol		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	16572858	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1075220			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia;	Aspirin			S	Oral			Not Reported
	Diclofenac Potassium			S	Unknown			Actavis
	Diclofenac Potassium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Ibuprofen			S	Unknown			Actavis
	Sulfamethoxazole And Trimethoprim			S	Unknown			Teva
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold Radioactive Colloidal			S	Other			Not Reported
	Gold Radioactive Colloidal			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Motrin	S	Unknown	Not Reported
	Naprosyn [Naproxen]	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Vitamin C	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Acetylsalicylic Acid/Vitamin C	S	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	16583278	EXPEDITED (15-DAY)		HO, LT, OT	US-AUROBINDO-AUR-APL-2019-039093		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Tachycardia; Toxicity To Various Agents; West Nile Viral Infection	Methylprednisolone			S	Unknown	Unk		Aurobindo
	Prednisone			S	Unknown	6 Milligram (Part Of A Regimen That Involved Tapering Of The Dose)		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Sulfamethoxazole And Trimethoprim			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	16748703	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-082588		60 YR	Male	CAN

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

Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased	Eliquis	S	Unknown	Unk, Bid	Bristol Myers Squibb
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	16908147	EXPEDITED (15-DAY)		CA, HO, OT	JP-ADVANZ PHARMA-201910001007			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Palate; Foetal Exposure During Pregnancy; Foetal Heart Rate Deceleration Abnormality; Neonatal Asphyxia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Transplacental	400 Mg, Qd		Concordia
	Magnesium Oxide			C		Unk		Not Reported
	Kefral			C		Unk		Not Reported
	Oxytocin			C		Unk		Not Reported
	Cefmetazole Sodium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17046755	EXPEDITED (15-DAY)		DE, HO, LT, OT	JP-ADVANZ PHARMA-201911001684			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arrhythmia; Bone Marrow Failure; Breath Sounds Abnormal; Cardiac Failure; Cytomegalovirus Test Positive; Decreased Appetite; Diarrhoea; Face Oedema; General	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Valganciclovir Hydrochloride			S	Oral	1t/1x		Not Reported
	Valganciclovir Hydrochloride			S	Oral	2t/2x		Not Reported
	Mycophenolate Mofetil			C		2 Mg, Qd		Not Reported
	Takecab			C		Unk 20		Not Reported

Physical Health Deterioration; Palpitations; Platelet Count Decreased; Stress Cardiomyopathy; Ventricular Extrasystoles; Ventricular Tachycardia	Predonine	C	Unk,5	Not Reported
	Predonine	C	Unk (Dose Reduced)	Not Reported
	Calonal	C	Unk, 200	Not Reported
	Baktar	C	Unknown	Not Reported
	Azosemide	C	Unk,30	Not Reported
	Bisoprolol Fumarate	C	Unk,2.5	Not Reported
	Torasemide	C	Unk,4	Not Reported
	Feburic	C	Unk,20	Not Reported
	Samsca	C	Unk,7.5	Not Reported
	Pursennid	C	Unk,12	Not Reported
	Mexitil	C	Unk,100	Not Reported
	Mercazole	C	Unk,5	Not Reported
	Lipovas	C	Unk,5	Not Reported
	Mevalotin	C	Unk,10	Not Reported
	Unisia	C	Unk	Not Reported
	Imidapril Hydrochloride	C	Unk,5	Not Reported
	Myslee	C	Unk,5	Not Reported
	Toyofarol	C	Unk,0.5	Not Reported
	Mycophenolate Mofetil	C	Unk	Not Reported
	Es Polytamin	C	Unk	Not Reported
	Bio-Three	C	Unk	Not Reported
	Hangeshashinto	C	Unk	Not Reported
	Albumin Tannate	C	Unk	Not Reported
	Nexium	C	Unk,20	Not Reported
	Polaprezinc	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17149900	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191214503			Female	CAN

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

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Reactine (Cetirizine Dihydrochloride)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17189316	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6042			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17189592	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053899		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		1 Dosage Form, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Simponi			S				Not Reported
	Prednisone			C	Oral			Not Reported
	Lyrica			C				Not Reported
	Xeljanz			C	Oral	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17190342	EXPEDITED (15-DAY)		DE, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6054		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Aurothiomalate De Sodium			S	Unknown			Not Reported
	Aurothiomalate De Sodium			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported

Rituxan	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab;Urelumab	C	Unknown		Not Reported
Simponi	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17190465	EXPEDITED (15-DAY)			AU-ALKEM LABORATORIES LIMITED-AU-ALKEM-2018-10002			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use; Pleural Effusion; Pleuritic Pain	Mycophenolate Mofetil			S	Unknown	Unknown		Alkem
	Cyclophosphamide			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methylprednisolone			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17190468	EXPEDITED (15-DAY)			AU-ALKEM LABORATORIES LIMITED-AU-ALKEM-2018-10009		26 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Tacrolimus			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported

	Hydroxychloroquine			S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17190490	EXPEDITED (15-DAY)		OT	AR-ALKEM LABORATORIES LIMITED-AR-ALKEM-2019-07459		32 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective; Granulomatous Dermatitis; Interstitial Lung Disease	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17190673	EXPEDITED (15-DAY)			AR-ALKEM LABORATORIES LIMITED-AR-ALKEM-2018-11108		32 YR	Female	ARG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17190918	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019548253			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver	Amlodipine Besilate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Function Test Increased; Skin Exfoliation	Etanercept	S	Unknown	Unk	Pfizer
	Hydroxychloroquine Sulfate	S	Oral	300 Mg, 1x/Day	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17191255	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019546190			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous			Unknown
	Enbrel			S	Subcutaneous	40 Mg, Weekly		Pfizer
	Azathioprine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Monthly		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	0.75 Mg, Monthly		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17191497	NON-EXPEDITED			US-PFIZER INC-2019551848		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Nausea	Doxycycline Hyclate			S		Unk		Pfizer

	Morphine Sulfate	S	Unk	Unknown
	Hydroxychloroquine	S	Unk	Not Reported
	Tramadol	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17191748	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2019053613		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Cimzia			S	Subcutaneous	200 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Cefazolin			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Weekly (Qw)		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Milligram, Weekly (Qw)		Not Reported
	Remicade			S		Powder For Solution Intravenous		Not Reported
	Rituxan			S		Solution Intravenous		Not Reported
	Amlodipine			C				Not Reported
	Arava			C				Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C				Not Reported
	Methotrexate			C		Unk		Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Tofacitinib Citrate			C				Not Reported
	Viread			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17191762	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019546164			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, 1x/Day		Pfizer
	Actemra			S	Unknown	8.0 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17191784	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019546234			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Enbrel			S	Subcutaneous			Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Dec-2019	17193564	EXPEDITED (15-DAY)		OT	DE-ALLERGAN-1952077US			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Prednisolone Unk			S	Unknown	Unk		Allergan
	Quensyl			S		5 Mg		Not Reported
	Benlysta			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	15665897	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-BI-05		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic;	Mobicox			S	Unknown			Boehringer Ingelheim
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	15674128	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574075-00		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	15927623	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2019003397		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disability; Disease Recurrence; Drug Ineffective; Dyspnoea; Impaired Work Ability; Insomnia; Joint Lock; Joint Swelling; Limb Discomfort;	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Weekly (Qw)		Not Reported
	Arava			S	Oral	200 Mg, Once Daily (Qd)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg Once Daily		Not Reported

Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Peripheral Swelling; Physical Disability; Rash; Rheumatoid Arthritis; Skin Mass; Sleep Disorder; Therapeutic Product Effect Decreased; Therapy Non-Responder	Actemra	S	Intravenous (not otherwise specified)	8 Milligram, Monthly (Qm)	Not Reported
	Humira	S	Subcutaneous	40 Mg, Ev 2 Weeks(Qow)	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S		200 Milligram	Not Reported
	Methotrexate	S	Oral	25 Mg, Monthly (Qm)	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Weekly (Qw)	Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	200 Milligram, Once Daily (Qd)	Not Reported
	Prednisone	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2 Gram Every 6 Months	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, 2x/Day (Bid)	Not Reported
	Risedronate Sodium	C		Unk	Not Reported
	Ergocalciferol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	16731220	EXPEDITED (15-DAY)		DE, HO, OT	CA-TEVA-2019-CA-1095844		16 YR	Female	CAN

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

Abdominal Pain Upper; Clear Cell Renal Cell Carcinoma; Complications Of Bone Marrow Transplant; Hair Follicle Tumour Benign; Hepatosplenic T-Cell Lymphoma; Hypotension; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Pyrexia; Splenomegaly; T-Cell Lymphoma; Tachycardia; Thrombocytopenia	Methotrexate	S	Unknown		Barr
	Ciclosporin	S	Unknown		Ivax
	Ciclosporin	S			Ivax
	Etoposide	S	Unknown		Teva
	Etoposide	S			Teva
	Anakinra	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	.7143 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S			Not Reported
	Tacrolimus	S	Unknown		Not Reported
	Thalidomide	S	Oral		Not Reported
	Etanercept	S	Unknown		Not Reported
	Etanercept	S			Not Reported
	Kineret 100mg Per Syringe Single-Use,Preservative-Free Prefilled Syrin	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	33.3333 Milligram Daily;	Not Reported
	Remicade	S			Not Reported
	Acetazolamide	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Actavis
	Amlodipine	S	Unknown		Teva
	Azathioprine	S	Unknown		Not Reported
	Azathioprine	S			Not Reported
	Azathioprine	S			Not Reported
	Calcium Carbonate	S	Unknown		Not Reported
	Cyclophosphamide	S	Unknown		Not Reported
	Enalapril	S	Unknown		Not Reported
	Ferric Hydroxide Polymaltose Complex	S	Unknown		Not Reported
	Ferrous Fumarate	S	Unknown		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Insulin	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Barr
	Leflunomide	S		Barr
	Metformin	S	Unknown	Actavis
	Nutropin	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Actavis
	Protropin	S	Intramuscular	Not Reported
	Ranitidine	S	Unknown	Not Reported
	Sulfamethoxazole	S	Unknown	Not Reported
	Testosterone	S	Unknown	Not Reported
	Etoposide	C		Not Reported
	Kineret 100mg Per Syringe Single-Use,Preservative-Free Prefilled Syrin	C		Not Reported
	Tacrolimus	C		Not Reported
	Thalidomide Celgene -50 Mg Capsula Rigida - Celgene Europe Limited	C		Not Reported
	Thalomid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	16757033	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017396871		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased	Eliquis			S	Unknown	Unk, Bid		Not Reported
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
	Leflunomide	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	16791977	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2019-US-1105366		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Cardiac Arrest; Intentional Overdose; Metabolic Acidosis; Pulmonary Oedema; Pupil Fixed; Renal Failure; Toxicity To Various Agents; Unresponsive To Stimuli	Hydroxychloroquine			S	Oral	Approximately 60 Tablets Of 200 Mg		Teva
	Naproxen			C	Oral	Several Amount Of 750mg Naproxen		Not Reported
	Ibuprofen			C	Oral	Unknown Quantity Of 200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	16820266	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-19K-028-2927400-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Triamcinolone			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported

Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Hydroxychloroquine Sulfate Tablets, Usp	Not Reported
	Kineret	S	Subcutaneous	Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Infliximab	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S			Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Naproxen	S	Unknown		Not Reported
	Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Immunoglobulin (Immunoglobulin Human Normal)	S			Not Reported
	Gammagard	S	Intravenous (not otherwise specified)		Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Suspension Intraarticular	Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Gamastan	S	Intravenous (not otherwise specified)	Solution Intramuscular	Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Triamcinolone Hexacetonide	C	Intra-articular	Suspension Intraarticular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17194256	EXPEDITED (15-DAY)		OT	CA-ROCHE-2498502		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration 731.0		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration 4.0 Year(S)		Not Reported
	Methotrexate			S	Unknown	Therapy Duration 10.0 Month(S)		Not Reported
	Methotrexate			S	Unknown	Therapy Duration 9.0 Year(S)		Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration 731.0		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration 10.0 Month(S)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration 4.0 Year(S), Powder For Solution Intravenous		Not Reported
	Sodium Aurothiomalate			S	Unknown	Therapy Duration 4.0 Year(S)		Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17194679	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1155789		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Tocilizumab	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Etanercept	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17194686	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155796		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17194714	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201908-001780			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis; Pneumonia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd, Film-Coated Tablet		Concordia
	Mycophenolate Mofetil			S	Oral	1000 Mg, Bid		Not Reported

Prograf	S	Oral	0.5 Mg, Qd		Not Reported
Losartan Potassium	S	Oral	50 Mg, Qd		Not Reported
Itraconazole	S	Oral	200 Mg, Qd		Not Reported
Nexium 1-2-3	S	Oral	20 Mg, Qd		Not Reported
Predonine	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17194989	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155914			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Off Label Use; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195082	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201912002944			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthralgia; Asthenia; Blood Glucose Increased; Contusion; Diarrhoea; Dizziness; Fall; Fall; Fatigue; Fatigue; Fungal Infection; Gait Disturbance; Gastric Disorder; Immunodeficiency; Joint	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Citrate Free		Not Reported
	Humira			S	Subcutaneous	(1 In 1 Wk)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S		Unk		Not Reported

Range Of Motion Decreased; Migraine; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Pain In Extremity; Pain In Extremity; Pneumonia; Rash Papular; Respiratory Disorder; Sensitivity To Weather Change; Stress; Therapeutic Response Shortened; Vaginal Haemorrhage; Viral Infection; Visual Impairment; Vomiting; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195088	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-201912003110			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Chest Pain; Respiratory Distress; Tachycardia	Hydroxychloroquine			S	Unknown	200 Mg X2		Concordia
	Escitalopram			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195133	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported

	Actemra	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195157	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155787			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195190	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1155815		61 YR	Female	CAN

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

Alanine Aminotransferase Increased; Drug Ineffective; Exostosis; Osteoarthritis; Pain In Extremity; Pulmonary Thrombosis; Thrombosis	Leflunomide		S	Oral	20 Milligram Daily;	Barr
	Xeljanz		S	Oral		Not Reported
	Methotrexate		S	Oral		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Pantoprazole		C	Unknown	40 Milligram Daily;	Not Reported
	Pravastatin		C	Unknown	40 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195191	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155809			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Plaquenil			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195442	EXPEDITED (15-DAY)		HO, OT	CN-ALKEM LABORATORIES LIMITED-CN-ALKEM-2019-05830		27 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemophagocytic Lymphohistiocytosis; Infection	Mycophenolate Mofetil			S	Unknown	Daily		Alkem
	Prednisolone			S	Oral	Daily		Not Reported
	Prednisolone			S	Oral	10 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Daily		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195657	NON-EXPEDITED		OT	NVSC2019US077986		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Vision Blurred	Hydroxychloroquine			S	Unknown	400 Mg, Qd (Daily Dose/Real Body Weight: 4.94 Mg/Kg)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17195982	EXPEDITED (15-DAY)		OT	CA-ROCHE-2498563			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Tenofovir Disoproxil Fumarate			C				Not Reported
	Xeljanz			C				Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17196257	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1155963			Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Hepatitis Acute; Lymphoma	Leflunomide		S	Unknown	Barr
	Methotrexate		S	Unknown	Barr
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17196270	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1156035		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Shoulder Operation; Therapeutic Response Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17196357	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155788			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Lyrica			S	Oral	300 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17196541	NON-EXPEDITED		OT	NVSC2019US077967		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	4.55 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17196673	EXPEDITED (15-DAY)		DS	CA-PFIZER INC-2019550573			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Condition Aggravated; Fatigue; Joint Swelling; Ocular Toxicity; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk, Weekly		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			C				Not Reported
	Diclofenac			C		50 Mg, 2x/Day		Not Reported
	Hydroxychloroquine			C	Oral	400 Mg, 1x/Day		Not Reported
	Indocid [Indometacin]			C		3 Every 1 Day(S)		Not Reported
	Leflunomide			C	Oral	Unk Unk, 1x/Day		Not Reported
	Naproxen			C		500 Mg, 1 Every 6 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17196849	NON-EXPEDITED		OT	NVSC2019US077958		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Retinopathy; Vision Blurred	Hydroxychloroquine			S	Unknown	5.44 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197262	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155848			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197272	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1155879		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Aleve	C		Not Reported
	Arava	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197273	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155849		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197281	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1156027			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Red Blood Cell Sedimentation Rate Increased; Urticaria	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Parenteral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ciclosporin			C				Not Reported

	Methotrexate	C	Parenteral		Not Reported
	Minocycline	C			Not Reported
	Penicillamine	C			Not Reported
	Phenylbutazone	C			Not Reported
	Prednisolone	C	6 Milligram Daily;		Not Reported
	Prednisone	C	12 Milligram Daily;		Not Reported
	Tofacitinib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197487	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1156070		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C	Unknown			Not Reported
	Gabapentin			C	Oral			Not Reported
	Nitroglycerin			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197491	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155902		55 YR	Female	CAN

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

Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Leflunomide	S	Unknown			Barr
	Methotrexate	S	Unknown			Barr
	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Aspirin/00002701/	C	Unknown			Not Reported
	Cymbalta	C	Unknown			Not Reported
	Hydromorphone	C	Unknown			Not Reported
	Synthroid	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197506	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155856			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Intolerance; Drug Intolerance; Finger Deformity; Foot Deformity; Gait Disturbance; Infection; Pancytopenia	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197507	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1156033			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Fatigue; Hand Deformity; Infection; Pain; Therapy Non-Responder	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Toradol			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C		2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197509	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155860			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Ill-Defined Disorder; Neuropathy Peripheral; Stomatitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Subcutaneous	26 Milligram Daily;		Not Reported
	Tofacitinib			S	Unknown	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197529	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027524			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness;	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Certolizumab Pegol	S	Unknown	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Advair	C		Unk	Not Reported
	Allopurinol	C		Unk	Not Reported
	Atrovent Hfa	C		Unk (Aerosol)	Not Reported
	Codeine	C		Unk	Not Reported
	Cyclobenzaprine Hydrochloride	C		Unk	Not Reported
	Dilaudid	C		Unk	Not Reported
	Hydromorphone Hydrochloride	C		Unk	Not Reported
	Ibuprofen	C		Unk	Not Reported
	Leucovorin Calcium	C		Unk	Not Reported
	Nexium Mups [Esomeprazole Magnesium]	C		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C		Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Ventolin Hfa	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2019	17197849	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3200633-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Bursitis; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity;	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Gastrectomy; Hypothyroidism; Mammoplasty; Obesity; Osteoarthritis; Osteopenia; Phlebectomy; Synovitis; Therapeutic Product Effect Incomplete	Simponi	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Stelara	S	Unknown	Not Reported
	Stelara	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Penicillin	S	Unknown	Not Reported
	Quaternium-15	S	Unknown	Not Reported
	Lasix	C		Not Reported
	Synthroid	C		Not Reported
	Montelukast	C		Not Reported
	Bricanyl	C		Not Reported
	Enbrel	C		Not Reported
	Cetirizine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2019	15625545	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558391-00		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Duration 365.0		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Apo-Leflunomide	S	Oral	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2019	17198137	EXPEDITED (15-DAY)		HO, OT	PT-ACCORD-164980		26 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection Reactivation; Ischaemic Stroke; Varicella Zoster Virus Infection; Vasculitis	Mycophenolic Acid			S				Accord
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2019	17198644	EXPEDITED (15-DAY)		OT	CA-ROCHE-2498601			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip	Therapy Duration:365.0		Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported

Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cortisone	S	Unknown		Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S			Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Fosamax	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Golimumab	S	Unknown		Not Reported
	Golimumab	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydrocortisone Acetate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral	Therapy Duration:11.0 Year(S)	Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S			Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	Therapy Duration:365.0	Not Reported
	Sulfasalazine	S	Unknown	Therapy Duration:365.0	Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Topicort [Desoximetasone]	S	Unknown		Not Reported
	Topicort [Desoximetasone]	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C			Not Reported
	Salazopyrina	C			Not Reported
	Tofacitinib Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	14938512	NON-EXPEDITED			US-PFIZER INC-2018215382		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Lyrica			S	Oral	75 Mg, 3x/Day		Pfizer
	Lyrica			S				Pfizer
	Lyrica			S				Pfizer
	Lyrica			S				Pfizer
	Plaquenil			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	16842391	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2797897-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use;	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17041153	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201802-000660			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypercholesterolaemia; Low Density Lipoprotein Increased; Platelet Count Decreased; Retinal Tear; Visual Field Defect	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Prednisolone			S	Oral	60 Mg, Qd		Not Reported
	Prednisolone			S	Oral	50 Mg, Qd		Not Reported
	Prednisolone			S	Oral	45 Mg, Qd		Not Reported
	Prednisolone			S	Oral	40 Mg, Qd		Not Reported
	Prednisolone			S	Oral	35 Mg, Qd		Not Reported
	Prednisolone			S	Oral	30 Mg, Qd		Not Reported
	Prednisolone			S	Oral	27.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	25 Mg, Qd		Not Reported
	Prednisolone			S	Oral	22.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd		Not Reported
	Prednisolone			S	Oral	17.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported
	Prednisolone			S	Oral	12.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Prednisolone			S	Oral	9 Mg, Qd		Not Reported
	Prednisolone			S	Oral	8 Mg, Qd		Not Reported
	Prednisolone			S	Oral	7 Mg, Qd		Not Reported
	Prednisolone			S	Oral	6 Mg, Qd		Not Reported

	Sulfamethoxazole/Trimethoprim	S	Oral	1 Dosage Form, Qd	Not Reported
	Amlodipine	S	Oral	10 Mg, Qd	Not Reported
	Cellcept	C		Unk	Not Reported
	Onealfa	C		Unk	Not Reported
	Onealfa	C			Not Reported
	Bonalon	C		Unk	Not Reported
	Bonalon	C			Not Reported
	Calblock	C		Unk	Not Reported
	Avapro	C		Unk	Not Reported
	Carvedilol	C		Unk	Not Reported
	Natrix	C		Unk	Not Reported
	Nexium	C		Unk	Not Reported
	Nexium	C			Not Reported
	Famotidine	C		Unk	Not Reported
	Famotidine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17124062	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2019-CA-1146237		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis;	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Minocycline			S	Unknown			Actavis
	Minocycline			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported

Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis; Urticaria	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Ilaris Single-Use Vial	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Cannabis Sativa	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Rituximab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17177631	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-			Female	CAN

CA2019230172

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Mg		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17194628	EXPEDITED (15-DAY)		OT	CA-ROCHE-2498579		56 YR	Female	CAN

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

Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Actonel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17199790	EXPEDITED (15-DAY)			GB-ALKEM LABORATORIES LIMITED-GB-ALKEM-2018-10791		49 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapy Non-Responder	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17199807	EXPEDITED (15-DAY)		HO, OT	GB-ALKEM LABORATORIES LIMITED-GB-ALKEM-2018-09566		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Glucose Tolerance Impaired;	Mycophenolate Mofetil			S	Unknown	500 Mg, Bid		Alkem
	Mycophenolate Mofetil			S	Unknown	750 Mg, Bid		Alkem

Maternal Exposure During Breast Feeding; Otitis Externa; Staphylococcal Infection; Therapy Partial Responder	Mycophenolate Mofetil		S	Unknown	500 Mg, Bid	Alkem
	Tacrolimus		S	Unknown	2 Mg, Qd	Not Reported
	Tacrolimus		S	Unknown	3 Mg, Bid	Not Reported
	Methylprednisolone		S	Intravenous (not otherwise specified)	500 Mg, Per Dose	Not Reported
	Prednisolone		S	Oral	20 Mg, Qd	Not Reported
	Prednisolone		S	Oral	20 Mg, Qd	Not Reported
	Prednisolone		S	Oral	30 Mg, Qd	Not Reported
	Azathioprine		S	Unknown	50 Mg, Qd	Not Reported
	Azathioprine		S	Unknown	25 Mg, Qd	Not Reported
	Azathioprine		S	Unknown	50 Mg, Qd	Not Reported
	Gliclazide		S	Unknown	Unk	Not Reported
	Insulin		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Hydroxychloroquine		S	Unknown	200 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17199911	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1156024			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Certolizumab Pegol			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Advair			C				Not Reported

Product Effect Decreased; Therapeutic Product Effect Decreased	Allopurinol	C	Not Reported
	Atrovent Hfa	C	Not Reported
	Plaquenil	C	Not Reported
	Sulfasalazine	C	Not Reported
	Ventolin Hfa	C	Not Reported
	Xeljanz	C	Not Reported
	Codeine	C	Not Reported
	Cyclobenzaprine Hydrochloride	C	Not Reported
	Dilaudid	C	Not Reported
	Hydromorphone Hydrochloride	C	Not Reported
	Ibuprofen	C	Not Reported
	Leucovorin Calcium	C	Not Reported
	Nexium Dr	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17199926	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3205492-00		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17199963	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155835		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Unknown			Barr
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Gold			S	Unknown			Not Reported

	Arava	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Methotrexate	S	Oral	25 Milligram Daily;	Not Reported
	Methotrexate	S	Oral	25 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17200584	EXPEDITED (15-DAY)		HO, LT, OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-06269		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
West Nile Viral Infection	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Rituximab			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Trimethoprim–Sulfamethoxazole			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17200606	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-07147			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Leukopenia	Mycophenolate Mofetil			S	Oral	Unk		Alkem
	Tacrolimus			S	Topical	Unk		Not Reported
	Azathioprine			S	Oral	Unk		Not Reported
	Cyclosporine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Thalidomide			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17200636	EXPEDITED (15-DAY)		HO, LT, OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-07074		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Bone Marrow Failure; Hypercalcaemia; Lymphoproliferative Disorder	Mycophenolate Mofetil			S	Unknown	1000 Milligram		Alkem
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Once Weekly		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17200771	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201912003102			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Gait Disturbance; Paraesthesia; Skin Fissures	Hydroxychloroquine			S		Unk,Plaquenil		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17200793	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019233563			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Methotrexate			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Arava	S	Unknown	Unk		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Fosamax	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17201567	EXPEDITED (15-DAY)		OT	DE-BAUSCH-BL-2019-066044		54 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Prednisolon			S	Unknown			Bausch And Lomb
	Quensyl			S	Unknown			Not Reported
	Benlysta Solution For Injection In Pre-Filled Pen			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17201727	NON-EXPEDITED		OT	NVSC2019US077983		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Vision Blurred	Hydroxychloroquine			S	Unknown	6.07 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17201728	NON-EXPEDITED		OT	NVSC2019US077969		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	8.25 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17201878	EXPEDITED (15-DAY)		HO, OT	CA-MYLANLABS-2019M1126876		1 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Synthroid			S		Unk		Mylan
	Cambia			S	Oral	75 Milligram, Bid		Mylan
	Cambia			S	Oral	1 Dosage Form		Mylan
	Cambia			S	Oral	2 Dosage Form, Qd		Mylan
	Diclofenac Potassium			S	Oral	Unk		Mylan
	Folic Acid			S		Unk		Mylan
	Hydroxychloroquine Sulfate			S	Oral	1 Dosage Form, Qd		Mylan
	Lisinopril			S		Unk		Mylan
	Lisinopril			S		Unk		Mylan
	Methotrexate			S	Subcutaneous	1 Dosage Form, Qw		Mylan
	Pantoprazole			S		Unk		Mylan
	Pantoprazole			S	Unknown	Unk		Mylan
	Sulfasalazine			S	Oral	1 Gram, Bid		Mylan
	Xeljanz			S	Oral	2 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17201920	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019548402		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal	Enbrel			S		50 Mg, Unk		Pfizer
	Methotrexate Sodium			S		5 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer

Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Cimzia	S		200 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	5 Mg, Unk	Not Reported
	Leflunomide	S	Oral	10 Mg, Unk	Not Reported
	Orencia	S		750 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown	50 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17202788	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019550599			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Polyneuropathy	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17202838	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019550697			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Drug Ineffective; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S				Pfizer
	Azithromycin			S				Pfizer
	Xeljanz			S		5 Mg, 2x/Day		Pfizer
	Azathioprine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Metoprolol			S				Not Reported
	Naproxen			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17202839	NON-EXPEDITED			US-PFIZER INC-2019551329		76 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Doxycycline Hyclate			S		Unk		Pfizer
	Levofloxacin			S		Unk		Pfizer
	Azathioprine			S		Unk		Not Reported
	Certolizumab			S		Unk		Not Reported
	Cefalexin			S		Unk		Not Reported
	Chlorphenamine			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17202841	NON-EXPEDITED			US-PFIZER INC-2019551452		65 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Nitrofurantoin			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17203089	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2019M1126387			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pancytopenia; Pneumonia; Sepsis; Splenomegaly; Systemic	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Quensyl			S	Unknown	200 Milligram, Bid		Mylan

Lupus Erythematosus; Urinary Tract Infection	Abatacept	S	Subcutaneous	125 Milligram, Qwk	Mylan
	Tilidine Hydrochloride	C	Unknown	Unk, Qd	Mylan
	Pantozol /01263204/	C	Unknown	Unk, Qd	Mylan
	Cellcept /01275102/	C	Unknown	Unk	Mylan
	Decortin H	C	Unknown	40 Milligram	Mylan
	Torem /01036501/	C	Unknown	5 Milligram	Mylan
	Ibuprofen	C	Unknown	600 Milligram, Qd	Mylan
	Amlodipin /00972401/	C	Unknown	2.5 Milligram	Mylan
	Vigantoletten	C	Unknown	1000 International Unit	Mylan
	Clexane	C	Subcutaneous	0.4 Milliliter	Mylan
	Delix /00885601/	C	Unknown	2.5 Milligram	Mylan
	Prednisolon /00016201/	C	Unknown	75 Milligram	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17203670	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1155883		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Desoximetasone			C	Unknown	10 Milligram Daily;		Not Reported
	Gold			C	Unknown			Not Reported

	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Dec-2019	17204380	NON-EXPEDITED		OT	NVSC2019US077964		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Vitreous Floaters	Hydroxychloroquine			S	Unknown	5.33 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	13226892	EXPEDITED (15-DAY)		OT	CA-SA-2015SA125523		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Dyspnoea; Eating Disorder; Fatigue; Infection; Intraocular Pressure Increased; Joint Swelling; Nausea; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Weight Decreased	Arava			S	Unknown	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	13362332	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP008455			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Prednisone			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Ramipril			S	Oral	Unk, Qd		Apotex
	Ramipril			S	Oral	Unk, Every 1 Day(S)		Apotex

	Dorzolamide ,Timolol	S	Unknown	Unk Unk, Bid	Apotex
	Dorzolamide ,Timolol	S	Unknown	1 Df, Bid	Apotex
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Levothyroxine	S	Unknown	Unk, Qd	Not Reported
	Levothyroxine	S	Unknown	1 Df, Every 1 Day(S)	Not Reported
	Methotrexate	S	Unknown	25 Mg, Q.Wk.	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk, Qd	Not Reported
	Tylenol /00020001/	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	15317340	EXPEDITED (15-DAY)		OT	CA-ROCHE-2173448			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra			S	Unknown	Therapy Duration: 5.0 Month(S)		Not Reported
	Arava			S	Oral	Therapy Duration: 2.0 Month(S)		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 7.0 Month(S)		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7.0 Month(S)		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	15982533	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014269			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	16449542	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018-03336		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Etanercept			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sodium Aurothiomalate			C	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown	Unknown		Not Reported
	Arava			C	Unknown	Unknown		Not Reported
	Actemra			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	16462022	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006323			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Apo-Acetaminophen			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Unk		Apotex
	Acetaminophen			S	Unknown	325 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	20 Ng, Unk		Apotex
	Leflunomide			S	Unknown	200 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Arava			S	Oral	20 Mg, Daily		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk (4 Every 1 Week)		Not Reported
	Enbrel			S	Unknown	40 Mg, Unk (4 Every 1 Week)		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	200 Mg, Unk		Not Reported
	Orencia			S				Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Tylenol /00020001/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	2000 Mg, Unk		Not Reported

Sulfasalazine	S	Oral	2000 Mg, Unk		Not Reported
Sulfasalazine	S	Oral	1000 Mg, Bid		Not Reported
Sulfasalazine	S	Oral	500 Mg, Bid		Not Reported
Sulfasalazine	S	Oral	2000 Mg, Unk		Not Reported
Synthroid	C	Unknown	Unk		Not Reported
Acetaminophen/Codein Phosphate	C	Unknown	Unk		Not Reported
Meloxicam	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	25 Df, Q.Wk.		Not Reported
Methotrexate	C	Unknown	Unk Unk, Q.Wk.		Not Reported
Methotrexate	C	Subcutaneous	Unk, 4 Every 1 Week		Not Reported
Methotrexate	C	Unknown	20 Mg, Q.Wk.		Not Reported
Methotrexate	C	Subcutaneous	25 Mg, Unk		Not Reported
Tylenol With Codeine No.3	C	Unknown	Unk		Not Reported
Leflunomide	C	Unknown	20 Mg, Qd		Not Reported
Hydromorphone Hcl	C	Unknown	Unk		Not Reported
Celebrex	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	16475127	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15886		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Oral	Unknown		Not Reported

Methotrexate	S	Parenteral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Plaquenil	S	Oral	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Remicade	S	Unknown	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
Rituxan	S	Subcutaneous	Unknown	Not Reported
Rituxan	S	Unknown	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown	Not Reported
Simponi	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown	Enteric Coated	Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unknown	Not Reported
Gold	S	Unknown	Unknown	Not Reported
Gold	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Prednisone	C	Unknown		Not Reported
Azathioprine	C	Unknown	Unknown	Not Reported
Ciclosporin/Cyclosporine	C	Unknown	Unknown	Not Reported
Minocycline	C	Unknown	Unknown	Not Reported

	Penicillamine		C	Unknown	Unknown	Not Reported
	Prednisolone		C	Unknown		Not Reported
	Actemra		C	Unknown	Unknown	Not Reported
	Tocilizumab		C	Unknown	Unknown	Not Reported
	D-Penicillamine		C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	16514254	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1060441		60 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Restlessness	Methotrexate			S	Unknown	20 Milligram, Qw		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	17.5 Milligram		Not Reported
	Benepali			S	Unknown	50 Milligram, Qw		Mylan
	Benepali			S	Unknown	50 Milligram,		Mylan
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram,		Mylan
	Chloroquine			C	Unknown	300 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17099186	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-112012			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

Cimzia	S	Subcutaneous			Not Reported
Enbrel	S	Subcutaneous			Not Reported
Folic Acid	S	Unknown	1 Milligram		Not Reported
Fosamax	S	Unknown			Not Reported
Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported
Methotrexate	S	Unknown			Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Apo Prednison	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous			Not Reported
Topicort [Hydrocortisone Acetate]	S	Topical			Not Reported
Sulfasalazine	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17204990	NON-EXPEDITED		OT	NVSC2019US077985		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photopsia; Retinopathy	Hydroxychloroquine			S	Unknown	6.77 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205318	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6063			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female;	Methotrexate (Trade Name			S	Unknown			Not Reported

Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Vomiting	Unknown)				
	Enbrel		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Meloxicam		C	Unknown	Not Reported
	Sulfasalazine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205327	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6061			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver Function Test Increased; Skin Exfoliation	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Amlodipine Besilate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205338	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6066			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205339	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6078		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205341	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6062			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205396	EXPEDITED (15-DAY)		DS	CA-ORION CORPORATION ORION PHARMA-TREX2019-6104			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Condition Aggravated; Fatigue; Joint Swelling; Ocular Toxicity; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Indocid			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205713	EXPEDITED (15-DAY)		HO	US-ADVANZ PHARMA-201912003112			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Fatigue; Nausea; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		800 Mg, Qd, 2 400 Mg Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205722	EXPEDITED (15-DAY)		HO	US-ADVANZ PHARMA-201912003095			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anxiety; Arthralgia; Arthritis; Condition Aggravated; Depression; Fall; Joint Injury	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Kevzara			S	Subcutaneous	200 Mg, Qow (Strength-200mg/1.14ml)		Not Reported
	Sarilumab Autoinjector			S	Unknown	Unk (Autoinjector)		Not Reported
	Diclofenac Sodium			C		Unk Mg		Not Reported
	Meloxicam			C		15 Unk		Not Reported

	Omeprazole	C	Unk Mg	Not Reported
	Oxybutynin Chloride	C	5 Mg	Not Reported
	Prednisone	C	Unk Mg	Not Reported
	Sertraline Hcl	C	100 Unk	Not Reported
	Simponi	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205881	EXPEDITED (15-DAY)		OT	SE-ALKEM LABORATORIES LIMITED-SE-ALKEM-2019-01287		58 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Intravenous Immunoglobulin (Ivig)			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17205941	EXPEDITED (15-DAY)		OT	GB-ADVANZ PHARMA-201912003094			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lupus; Central Nervous System Vasculitis; Infection; Liver Function Test Abnormal; Meningitis Enteroviral; Viral Upper Respiratory Tract Infection	Prednisolone			S		Unk		Concordia
	Prednisolone			S		7.5 Mg, Qd		Concordia
	Prednisolone			S				Concordia
	Rituximab			S		375 Mg/M2,2 Doses 14 Days Apart		Not Reported
	Rituximab			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

	Azathioprine	S	150 Mg	Not Reported
	Azathioprine	S	Unk	Not Reported
	Mycophenolate Mofetil	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17206018	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6073			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Diabetes Mellitus; Flank Pain; Leukaemia; Lymphoma; Neutrophil Count Increased; Splenomegaly; White Blood Cell Count Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cortisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17206132	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201702-000881			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Hypersensitivity; Nausea; Vomiting	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Lasix			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17206430	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6114		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Xeljanz		S	Oral	Not Reported
	Cimzia		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Oral	Not Reported
	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17206536	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-01939		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17206542	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-01938		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Colchicines			S	Unknown	Unk		Not Reported
	Sodium Thiosulfate			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17206617	EXPEDITED (15-DAY)			TW-ALKEM LABORATORIES LIMITED-TW-ALKEM-2018-10635		36 YR	Female	TWN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Mycophenolate Mofetil			S	Unknown	1000 Mg, Bid		Alkem
	Prednisolone			S	Unknown	30 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Felodipine			S	Unknown	5 Mg, Qd		Not Reported
	Irbesartan			S	Unknown	150 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17207300	EXPEDITED (15-DAY)		DE	NVSC2019TN080180			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17207519	EXPEDITED (15-DAY)		OT	NVSC2019TN080175			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17208104	NON-EXPEDITED			US-UCBSA-2017011447		58 YR	Female	USA

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

Drug Hypersensitivity	Zyrtec	S	Unknown Dose	Not Reported
	Certolizumab Pegol	S	Unknown Dose	Not Reported
	Acetaminophen	S	Unknown Dose	Not Reported
	Golimumab	S	Unknown Dose	Not Reported
	Levofloxacin	S	Unknown Dose	Not Reported
	Diphenhydramine Hcl	S	Unknown Dose	Not Reported
	Tramadol	S	Unknown Dose	Not Reported
	Hydromorphone	S	Unknown Dose	Not Reported
	Morphine	S	Unknown Dose	Not Reported
	Salicylate Sodium	S	Unknown Dose	Not Reported
	Diclofenac	S	Unknown Dose	Not Reported
	Oxycodone	S	Unknown Dose	Not Reported
	Hydrocodone	S	Unknown Dose	Not Reported
	Naproxen	S	Unknown Dose	Not Reported
	Clonidine	S	Unknown Dose	Not Reported
	Amlodipine	S	Unknown Dose	Not Reported
	Methylprednisolone	S	Unknown Dose	Not Reported
	Budesonide	S	Unknown Dose	Not Reported
	Nedocromil	S	Unknown Dose	Not Reported
	Cromolyn	S		Not Reported
	Montelukast	S	Unknown Dose	Not Reported
	Abatacept	S	Unknown Dose	Not Reported
	Adalimumab	S	Unknown Dose	Not Reported
	Methotrexate	S	Unknown Dose	Not Reported
	Dapsone	S	Unknown Dose	Not Reported
	Amoxicillin And Clavulanate Potassium	S	Unknown Dose	Not Reported
	Benzoic Acid	S	Unknown Dose	Not Reported
	Azithromycin	S	Unknown Dose	Not Reported
	Fluconazole	S	Unknown Dose	Not Reported

Clindamycin	S	Unknown Dose	Not Reported
Linezolid	S	Unknown Dose	Not Reported
Vancomycin	S	Unknown Dose	Not Reported
Ciprofloxacin	S	Unknown Dose	Not Reported
Cefdinir	S	Unknown Dose	Not Reported
Macrodantin	S	Unknown Dose	Not Reported
Heparin	S	Unknown Dose	Not Reported
Pantoprazole	S	Unknown Dose	Not Reported
Milk Of Magnesia	S	Unknown Dose	Not Reported
Fexofenadine	S	Unknown Dose	Not Reported
Sodium Hypochlorite	S	Unknown Dose	Not Reported
Prednisone	S	17 Mg Daily	Not Reported
Hydroxychloroquine	S	Unk	Not Reported
Sulindac	S		Not Reported
Albuterol	S		Not Reported
Gabapentin	S	Unk	Not Reported
Ramipril	S	Unk	Not Reported
Misoprostol	S	Unk	Not Reported
Rosuvastatin	S	Unknown Dose	Not Reported
Ranitidine	S	Unknown Dose	Not Reported
Teriparatide	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17208175	NON-EXPEDITED			US-UCBSA-2017031305			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia Of Chronic Disease; Blood Prolactin Decreased; Blood Thyroid Stimulating Hormone Decreased; Essential Hypertension; Fall;	Cimzia			S		Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S				Not Reported

Fibromyalgia; Gait Disturbance; Immunoglobulins Decreased; Insomnia; Osteoarthritis; Osteopenia; Pain; Rheumatoid Arthritis; Spondyloarthropathy; Synovitis; Type V Hyperlipidaemia	Prolia	S		Unk	Not Reported
	Methotrexate Sodium	S		Unk	Not Reported
	Tofacitinib Citrate	S		Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Remicade	S		Unk	Not Reported
	Humira	S		40 Mg, Weekly (Qw)	Not Reported
	Humira	S			Not Reported
	Orencia	S		Unk	Not Reported
	Plaquenil	S		Unk	Not Reported
	Arava	S	Oral	20 Mg Daily	Not Reported
	Aranesp	C			Not Reported
	Oxycodone	C			Not Reported
	Abilify	C		Unk	Not Reported
	Advair	C			Not Reported
	Atenolol	C			Not Reported
	Acetylsalicylic Acid	C			Not Reported
	Crestor	C			Not Reported
	Cytomel	C			Not Reported
	Dorzolamide Hcl	C		Unk	Not Reported
	Duloxetine Hydrochloride	C		Unk	Not Reported
	Duoneb	C			Not Reported
	Famotidine	C			Not Reported
	Finasteride	C			Not Reported
	Furosemide	C			Not Reported
	Gabapentin	C			Not Reported
	Leflunomide	C			Not Reported
	Lovaza	C			Not Reported
	Medrol	C			Not Reported
	Myrbetriq	C		Unk	Not Reported
	Nexium	C			Not Reported
	Fish Oil W/Tocopherol	C			Not Reported
	Oxycodone Hcl	C			Not Reported
	Prochlorperazine Maleate	C			Not Reported
	Relpax	C			Not Reported
	Singulair	C			Not Reported
	Soma	C			Not Reported

	Sulfazine Ec	C	Not Reported
	Synthroid	C	Not Reported
	Tamsulosin Hcl	C	Not Reported
	Topamax	C	Not Reported
	Topiramate	C	Not Reported
	Triamterene/Hctz	C	Not Reported
	Voltaren	C	Not Reported
	Xalatan	C	Not Reported
	Cymbalta	C	Not Reported
	Vicodin	C	Not Reported
	Vicodin	C	Not Reported
	Klonopin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17208493	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-120960			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17208514	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-120985			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17209192	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-121184			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Musculoskeletal Stiffness; Pain; Systemic Lupus Erythematosus	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17209201	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-121339			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

	Rituxan	S	otherwise specified) Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17209386	NON-EXPEDITED		OT	NVSC2019US077978		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Vision Blurred	Hydroxychloroquine			S	Unknown	4.88 Mg/Kg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17209496	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-39370			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Morphine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17209751	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019554720			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Etanercept			S				Pfizer
	Actemra			S				Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 1x/Day		Not Reported

	Prednisone		S	Oral	10 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17210008	NON-EXPEDITED		OT	NVSC2019US077973		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	6.06 Mg, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17210106	EXPEDITED (15-DAY)		OT	FR-ANIPHARMA-2019-FR-000271		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma	Anastrozole			S	Oral	1 Mg Daily		Ani
	Tahor			S	Oral	1 Df Daily 10 Mg		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported
	Coumadine			S				Not Reported
	Kardegic			S		1 Df Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17210369	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019554652			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Mg, 1x/Day		Not Reported
	Arava			C		20 Mg, 1x/Day		Not Reported
	Celebrex			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17210372	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019554709		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Unknown
	Enbrel			S		Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Actonel			S		35 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S		20 Mg, 1x/Day		Not Reported
	Plaquenil S			S		300 Mg, 1x/Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Hydroxychloroquine Sulfate			C		300 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17210655	EXPEDITED (15-DAY)		OT	CA-SA-2019SA355019		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication	Ranitidine			S	Unknown	Unk Unk, Unk		Sanofi
	Acetazolamide			S	Unknown	Unk Unk, Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk Unk, Unk		Not Reported
	Amlodipine (Salt Not Specified)			S	Unknown	Unk Unk, Unk		Not Reported
	Calcium Carbonate			S	Unknown	Unk Unk, Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk Unk, Unk		Not Reported
	Enalapril Maleate			S	Unknown	Unk Unk, Unk		Not Reported
	Ferric Hydroxide Polymaltose Complex			S	Unknown	Unk Unk, Unk		Not Reported

	Ferrous Fumarate	S	Unknown	Unk Unk, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk Unk, Unk	Sanofi
	Insulin Human Nos	S	Unknown	Unk Unk, Unk	Sanofi
	Leflunomide	S	Unknown	Unk Unk, Unk	Sanofi
	Leflunomide	S			Sanofi
	Metformin Hydrochloride	S	Unknown	Unk Unk, Unk	Not Reported
	Methotrexate	S	Unknown	Unk Unk, Unk	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Somatropine	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Prednisone	S	Unknown	Unk Unk, Unk	Not Reported
	Sulfamethoxazole	S	Unknown	Unk Unk, Unk	Not Reported
	Testosterone	S	Unknown	Unk Unk, Unk	Not Reported
	Azathioprine	S	Unknown	Unk Unk, Unk	Not Reported
	Azathioprine	S			Not Reported
	Azathioprine	S			Not Reported
	Ciclosporin	S	Unknown	Unk Unk, Unk	Not Reported
	Ciclosporin	S			Not Reported
	Protropin	S	Intramuscular	Unk Unk, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	1000 Mg, Qd	Not Reported
	Remicade	S			Not Reported
	Remicade	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17210983	EXPEDITED (15-DAY)		OT	CA-ROCHE-2415334			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Erythematosus	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulphathiazole	S	Unknown		Not Reported
	Prednisone	S	Intravenous (not otherwise specified)		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17210999	NON-EXPEDITED		OT	NVSC2019US077977		25 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy; Vision Blurred	Hydroxychloroquine			S	Unknown	730 G		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Dec-2019	17211028	EXPEDITED (15-DAY)		OT	CA-ROCHE-2505961		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Supeudol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	11437906	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-056744		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Arthropathy; Asthma; Back Pain; Condition Aggravated; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Inflammation; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Pneumonia; Pruritus; Pulmonary Fibrosis; Rheumatoid Arthritis; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Salicylates Nos			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methyl Salicylate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	12572852	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015113554		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, 4 Times/Wk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	12583397	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015363640		76 YR	Female	CAN

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

Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Off Label Use; Pain; Pain; Peripheral Swelling; Rheumatoid Arthritis	Enbrel	S	Subcutaneous	50 Mg, Unk		Pfizer
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Weekly		Unknown
	Methotrexate Sodium	S	Subcutaneous	20 Mg, 4 Times/Wk		Unknown
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Weekly		Unknown
	Methotrexate Sodium	S	Subcutaneous	20 Mg, 1x/Day		Unknown
	Sulfasalazine	S		1000 Mg, 2x/Day		Pfizer
	Humira	S	Subcutaneous	20 Mg, Daily		Not Reported
	Humira	S	Subcutaneous	Unk, 1x/Day		Not Reported
	Prednisone	S	Oral	5 Mg, Daily		Not Reported
	Arava	S		20 Mg, Daily		Not Reported
	Arava	S		20 Mg, Unk		Not Reported
	Plaquenil	S	Oral	200 Mg, 2x/Day		Not Reported
	Orencia	S		Unk		Not Reported
	Actemra	S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, Bid		Not Reported
	Apo-Prednisone	S	Oral	5 Mg, Qd		Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	12765196	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076380		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported

Apo-Metoprolol	S	Unknown			Not Reported
Naprosyn [Naproxen]	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Apo-Prednisone	S	Unknown			Not Reported
Metoprolol	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
Enbrel	S	Unknown	50 Mg, Qwk		Not Reported
Folic Acid	C	Unknown			Not Reported
Naproxen Sodium	C	Unknown			Not Reported
Rosuvastatin Calcium	C	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	12913921	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091769		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	13625794	EXPEDITED (15-DAY)		DS, HO, OT	US-SA-2017SA092060		67 YR	Female	USA

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

Asthenia; Bladder Catheterisation; Blood Calcium Increased; Blood Creatinine Increased; Blood Glucose Increased; Blood Iron Decreased; Blood Pressure Increased; Calcinosis; Cardiac Disorder; Cd4 Lymphocytes Decreased; Chest Pain; Condition Aggravated; Connective Tissue Inflammation; Diabetes Mellitus; Diarrhoea; Drug Monitoring Procedure Not Performed; Erythema; Fall; Fatigue; Gait Disturbance; Haemoglobin Decreased; Hand Fracture; Heart Rate Increased; Hyperparathyroidism Primary; Immunodeficiency; Infection; Joint Injury; Limb Injury; Loss Of Consciousness; Nephrolithiasis; Night Sweats; Optic Nerve Injury; Peripheral Swelling; Platelet Count Increased; Precancerous Cells Present; Pyrexia; Pyrexia; Renal Failure; Sinusitis; Skin Infection; Urinary Tract Infection; Visual Impairment; Weight Increased	Alemtuzumab	S	Intravenous drip	12 Mg, Qd	Sanofi
	Plaquenil	S	Unknown	Unk Unk,Unk	Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	15625955	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557437-00		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	16470270	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-058952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Intra-arterial	25 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd		Not Reported
Prednisone	S	Oral	Unk		Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Subcutaneous	500 Milligram		Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Bid		Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	16537815	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP017574		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Azathioprine			S	Unknown	Unk		Apotex
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Mycophenolate Mofetil			S	Unknown	Unk		Apotex
	Cyclosporine			S	Oral	Unk		Apotex
	Actemra			S	Unknown	64 Mg, Unk		Not Reported
	Actemra			S	Unknown	64 Mg, Q.Wk.		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Unk		Not Reported

Ciclosporin	S	Oral	Unk	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Q.Wk.	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Unk	Not Reported
Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
Enbrel	S	Unknown	50 Mg, Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	400 Mg, Q.Wk.	Not Reported
Hydroxychloroquine /00072603/	S	Unknown	Unk	Not Reported
Imuran /00001501/	S	Unknown	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Piroxicam	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	16657676	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1084356			Female	CAN

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

Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Azathioprine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Mycophenolate Mofetil	S	Unknown	Teva
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine /00072603/	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Imuran	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Lyrica	S	Unknown	Not Reported

	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	16867058	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-GSH201807-002707			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Mental Impairment; Overdose; Toxicity To Various Agents; Ventricular Tachycardia; Ventricular Tachycardia	Hydroxychloroquine			S	Unknown	36 G		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	16964715	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-201910001358			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Chills; Cushingoid; Decreased Appetite; Dehydration; Escherichia Urinary Tract Infection; Hypocalcaemia; Malaise; Nausea; Oedema Peripheral; Vomiting	Hydroxychloroquine			S	Unknown	Unk, Plaquenil		Concordia
	Avapro Hct			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg		Not Reported
	Prolia			S	Unknown	Unk; Single Dose Prefilled Syringe		Not Reported

Prolia	S	Unk, Recent Administration	Not Reported
Prednisolone	C	Unk	Not Reported
Prednisolone	C	25 Mg, Qd (Increased)	Not Reported
Prednisolone	C	15 Mg (Reducing Dose)	Not Reported
Prednisolone	C	10 Mg (Reducing Dose)	Not Reported
Prednisolone	C	5 Mg, Qd	Not Reported
Vitamin D	C	Unk	Not Reported
Calcium	C	Unk	Not Reported
Karvezide	C	Unk	Not Reported
Lyrica	C	Unk	Not Reported
Amlodipine	C	Unk	Not Reported
Amlodipine	C	10 Mg (Increased To 10 Milligram Mane)	Not Reported
Magnesium	C	Unk	Not Reported
Citracal Plus D	C	Unk	Not Reported
Panadol	C	Unk	Not Reported
Hydroxychloroquine	C	Unk	Not Reported
Folic Acid	C	Unk	Not Reported
Hydralazine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17166558	EXPEDITED (15-DAY)		HO	US-TEVA-2019-US-1153033		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Humoral Immune Defect; Lupus Enteritis; Meningoencephalitis Viral; West Nile Viral Infection	Hydroxychloroquine			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Methylprednisolone			S	Unknown	High-Dose		Not Reported
	Prednisone			S	Unknown	6 Milligram Daily; As Part Of A Regimen That Involved Tapering Of The		Actavis

			Dose	
	Mycophenolate Mofetil	S	Unknown	Teva
	Rituximab	S	Unknown	Not Reported
	Trimethoprim/Sulfamethoxazole	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17199605	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3205516-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Asthma; Back Pain; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Hypertension; Inflammation; Pain; Septic Shock; Synovitis; Urinary Tract Infection; Urosepsis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Salicylates Nos			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17211738	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509842			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Cimzia	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17212113	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508008		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Rituxan			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Elavil [Amitriptyline			C	Unknown			Not Reported

Hydrochloride]				
Hydrochlorothiazide	C	Unknown		Not Reported
Imitrex [Sumatriptan]	C	Unknown		Not Reported
Lyrica	C	Unknown		Not Reported
Premarin	C	Unknown		Not Reported
Sumatriptan Succinate	C	Unknown		Not Reported
Tenormin	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17212163	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-121431			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported

	Phosphate]					
	Prednisone	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid		Not Reported
	Tofacitinib Citrate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17212349	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1158545		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Esomeprazole			S	Unknown	40 Milligram Daily;		Teva
	Methotrexate			S	Subcutaneous			Barr
	Apo-Prednisone			S	Unknown	5 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate Tablets, Usp			S	Unknown	400 Milligram Daily;		Not Reported
	Folic Acid			S	Unknown	2 Dosage Forms Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17212721	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2019-08761		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Treatment Failure	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Lupin
	Doxycycline			S	Unknown	Unk		Lupin
	Pentoxifylline			C	Oral	400 Milligram, Tid		Not Reported
	Metformin			C	Unknown	Unk		Not Reported

	Rosuvastatin		C	Unknown	Unk	Not Reported
	Enalapril		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17212843	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-03698		8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Psoralen			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Immune Globulin (Iv)			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17212902	EXPEDITED (15-DAY)		OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM-2019-06160		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Mycophenolate Mofetil			S	Unknown	Unk, Titrated Up		Alkem
	Mycophenolate Mofetil			S	Unknown	1.5 Gram, Bid		Alkem
	Prednisone			S	Unknown	60 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported

	Cilostazol		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17213121	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6119			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Drug Ineffective; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17213603	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019555028		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	281 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported
	Apo-Prednisone			S	Unknown	2 Df, Unk		Not Reported
	Arava			S	Oral	20 Mg, Unk		Not Reported

Cimzia	S	Subcutaneous	200 Mg, 1 Every 2 Weeks		Not Reported
Folic Acid	S	Unknown	Unk Unk, Weekly		Not Reported
Humira	S	Subcutaneous			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17213794	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019557047		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Viral Infection	Celebrex			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17214515	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091702		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Finger Deformity; Gait Disturbance; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Enbrel	S	Unknown			Not Reported
Humira	S	Unknown	Unk		Not Reported
Humira	S	Unknown			Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown			Not Reported
Actemra	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	5 Milligram, Bid		Not Reported
Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17214861	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-122427		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Citirizine [Cetirizine Hydrochloride]			S	Unknown	10 Milligram		Not Reported
	Citirizine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram	Not Reported
Prednisone	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	1000 Milligram	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Diclofenac	C	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17215575	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-39441		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hyperhidrosis; Hyperhidrosis; Influenza; Multiple-Drug Resistance; Product Use Issue; Rheumatoid Arthritis;	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

Therapeutic Product Effect Incomplete; Wrong Technique In Product Usage Process	Prednisone	S	Oral			Not Reported
	Xeljanz	S	Oral			Not Reported
	Apo-Prednisone	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Celebrex	C	Unknown	Unknown		Not Reported
	Ergocalciferol	C	Unknown	Unknown		Not Reported
	Folic Acid	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17215819	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1952910US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Actonel			S	Oral	35 Mg, Q Week		Allergan
	Actonel			S	Unknown	Unk, Unknown		Allergan
	Enbrel			S	Unknown			Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Novo-Rythro			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Q Week		Not Reported
	Bupropion			C				Not Reported
	Cannabis Sativa			C	Unknown			Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Celebrex			C		200 Mg, Bid		Not Reported
	Ergocalciferol			C	Unknown	Unk Unk, Qd		Not Reported

Ergocalciferol	C	Unknown	Unk, Qd		Not Reported
Hydroxychloroquine	C	Oral	400 Mg, Qd		Not Reported
Wellbutrin	C	Unknown	300 Mg, Qd		Not Reported
Wellbutrin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17215889	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1953219US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Risedronate Sodium Unk			S		5 Mg		Allergan
	Actemra			S				Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Arava			S				Not Reported
	Celebrex			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Q Week		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Prednisolone			S				Not Reported
	Prednisone			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	500 Mg, Unk		Not Reported
	Cyclobenzaprine			C		10 Mg, Unk		Not Reported
	Desoximetasone			C		5 Mg, Qd		Not Reported
	Desoximetasone			C		5 Mg		Not Reported
	Leflunomide			C				Not Reported
	Prednisone Acetate			C		5 Mg, Qd		Not Reported
	Tylenol /00020001/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17216507	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-107103			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain	Celecoxib			S	Oral	200 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Dec-2019	17216592	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-122317		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	0.6 Milliliter, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	13224711	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890699		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported

Synovitis	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	14112535	EXPEDITED (15-DAY)		HO, OT	US-MALLINCKRODT-T201703249			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Agitation; Anxiety; Aphonia; Arthralgia; Arthritis; Asthenia; Back Pain; Blister; Body Temperature Increased; Bone Pain; Bradykinesia; Bronchitis; Cataract; Chemical Burn; Condition Aggravated; Confusional State; Contusion; Disturbance In Attention; Dizziness; Drug Abuse; Dry Skin; Dyskinesia; Dysphagia; Dyspnoea; Fall; Fatigue; Feeling Abnormal; Folliculitis; Food Poisoning; Gait	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 2 Times Per Week, (Wednesday And Saturday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 2 Times Per Week, (Wednesday And Saturday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 2 Times Per Week, (Wednesday And Saturday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 2 Times Per Week, (Wednesday And Saturday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 2 Times Per Week, (Wednesday And Saturday)		Mallinckrodt
	Repository Corticotropin			S	Subcutaneous	80 Units / 1 Ml, 2 Times		Mallinckrodt

Disturbance; Gastroenteritis Viral; Hair Texture Abnormal; Herpes Zoster; Hypersensitivity; Immunodeficiency; Incorrect Dose Administered; Influenza; Injection Site Haemorrhage; Injection Site Mass; Injection Site Pain; Insomnia; Kyphosis; Laryngeal Papilloma; Logorrhoea; Loss Of Consciousness; Malaise; Memory Impairment; Muscle Spasms; Muscular Weakness; Musculoskeletal Pain; Nasopharyngitis; Nervousness; Neuralgia; Pain In Extremity; Panic Attack; Peripheral Swelling; Pneumonia; Pollakiuria; Pruritus; Pulmonary Fibrosis; Pulmonary Oedema; Purpura; Pustule; Rash; Rectal Prolapse; Sarcoidosis; Scab; Skin Burning Sensation; Somnolence; Spinal Stenosis; Staphylococcal Infection; Toxic Encephalopathy; Tremor; Umbilical Haemorrhage; Urinary Tract Infection; Vein Disorder; Visual Impairment; Weight Decreased; Weight Increased; Wrong Technique In Product Usage Process	Injection			Per Week Wednesdays And Saturdays	
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml, 2 Times Per Week Wednesdays And Saturdays	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml, 2 Times Per Week (Wednesdays And Saturdays)	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml 2 Times Per Week Wednesday And Saturday	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml 2 Times Per Week Wednesday And Saturday	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml 2 Times Per Week Wednesday And Saturday	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml 2 Times Per Week Wednesday And Saturday	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml 2 Times Per Week Wednesday And Saturday	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml, 2 Times Per Week (Wednesdays And Saturdays)	Mallinckrodt
	Repository Corticotropin Injection	S	Subcutaneous	80 Units / 1 Ml, 2 Times Per Week (Wednesdays And Saturdays)	Mallinckrodt
	Morphine	S	Unknown	Unk	Mallinckrodt
	Prednisone	S	Unknown	20 Mg, One Week	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Levaquin	C	Unknown	For 14 Days	Not Reported
	Remeron	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	14778653	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2018157950		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Maculopathy; Retinopathy; Toxicity To Various Agents	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	15021181	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-031922		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Levofloxacin			S	Unknown	Unk		Aurobindo
	Metronidazole			S	Unknown	Unk		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Arthrotec			S	Intracardiac	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram, Once A Day		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythro Base			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Milligram, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	Unk		Not Reported
	Meperidine			S	Unknown	Unk		Not Reported

Plaquenil	S	Oral	400 Milligram, Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Apo Leflunomida	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	15462312	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA-2017SE55839		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Antinuclear Antibody Positive; Arthralgia; Atelectasis; Bursitis; Conjunctivitis; Contraindicated Product Administered; Crepitations; Cushingoid; Drug Ineffective; Dry Eye; Dry Mouth; Dyspnoea; Erythema; Eye Irritation; Eye Pain; Feeling Jittery; Fibromyalgia; Flank Pain; Haemoglobin Decreased; Impaired Work Ability; Infection; Interstitial Lung Disease; Joint Effusion; Joint Swelling; Lung Disorder; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neoplasm Malignant; Nodule; Ocular Hyperaemia; Pain; Pain In Extremity; Peripheral Swelling; Photophobia; Pleuritic Pain; Pneumonia; Pruritus; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis;	Vimovo			S	Oral	Unknown Dose		Not Reported
	Esomeprazole Magnesium			S	Oral			Not Reported
	Esomeprazole Magnesium			S	Unknown	Esomeprazole Magnesium Trihydrate		Not Reported
	Naproxen			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Naproxen			S	Oral	250.0mg Unknown		Not Reported
	Amoxicillin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Pantoloc			S	Oral	Daily		Not Reported
	Pantoloc			S	Oral	Unk		Not Reported
	Pantoloc			S	Oral	Unk		Not Reported
	Pantoloc			S	Unknown			Not Reported

Rheumatoid Nodule; Scleritis; Swelling Face; Synovial Cyst; Synovial Fluid Analysis; Tenderness; Tenosynovitis Stenosans; Therapeutic Product Effect Decreased; Thrombosis; Ulcer; Visual Impairment; Wheezing	Pantoloc	S	Unknown		Not Reported
	Pantoloc	S	Unknown		Not Reported
	Pantoloc	S	Unknown		Not Reported
	Alendronic Acid	S	Oral	Unknown Dose	Not Reported
	Amitriptyline	S	Oral		Not Reported
	Amitriptyline	S	Oral	Apo Amitriptyline	Not Reported
	Depo Medrol	S	Intra-articular	Daily	Not Reported
	Humira	S	Subcutaneous	40.0mg Unknown	Not Reported
	Imuran	S	Unknown	150.0mg Unknown	Not Reported
	Imuran	S	Unknown	150.0mg Unknown	Not Reported
	Lyrica	S	Oral		Not Reported
	Lyrica	S	Oral		Not Reported
	Lyrica	S	Oral		Not Reported
	Mobicox	S	Unknown		Not Reported
	Mobicox	S	Unknown	Unk	Not Reported
	Mobicox	S	Unknown	Unk	Not Reported
	Mobicox	S	Unknown	Apo-Meloxicam	Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral	Apo-Prednisone	Not Reported
	Prednisone	S	Oral	Apo-Prednisone	Not Reported
	Prednisone	S	Oral	Apo-Prednisone	Not Reported
	Prednisone	S	Oral	Apo-Prednisone	Not Reported
	Prednisone	S	Oral	Apo-Prednisone	Not Reported
	Prednisone	S	Oral	Apo-Prednisone	Not Reported

Ranitidine	S	Oral		Not Reported
Ranitidine	S	Oral		Not Reported
Septra	S	Unknown	Unknown Dose	Not Reported
Septra	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral	Tofacitinib Citrate, 10 Mg Daily	Not Reported
Xeljanz	S	Oral	Tofacitinib Citrate, 5 Mg Two Times Daily	Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Naproxen	S	Unknown	Apo-Naproxen	Not Reported
Naproxen	S	Unknown	Apo-Naproxen	Not Reported
Naproxen	S	Unknown	Apo-Naproxen	Not Reported
Naproxen	S	Unknown		Not Reported
Naproxen	S	Unknown		Not Reported
Naproxen	S	Unknown		Not Reported
Naproxen	S	Unknown		Not Reported
Naproxen	S	Unknown	Apo-Naproxen	Not Reported
Naproxen	S	Unknown	Apo-Naproxen	Not Reported
Apo Ranitidine	S	Oral		Not Reported
Apo Ranitidine	S	Oral	300 Mg, Weekly	Not Reported
Apo Ranitidine	S	Oral		Not Reported
Apo Ranitidine	S	Oral		Not Reported

Oxycocet	S	Unknown	Teva	Not Reported
Oxycocet	S	Unknown	Ratio	Not Reported
Oxycocet	S	Unknown	Unk	Not Reported
Oxycocet	S	Unknown	Unk	Not Reported
Apo-Alendronate	S	Unknown		Not Reported
Apo-Alendronate	S	Unknown	Fosamax	Not Reported
Bactrim	S	Unknown	Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	S	Unknown		Not Reported
Acetaminophen W/Oxycodone Hydrochloride	S	Unknown		Not Reported
Acetaminophen W/Oxycodone Hydrochloride	S	Unknown		Not Reported
Acetaminophen W/Oxycodone Hydrochloride	S	Unknown		Not Reported
Pregabalin	S	Oral		Not Reported
Pregabalin	S	Oral		Not Reported
Pregabalin	S	Oral		Not Reported
Azathioprine	S	Unknown		Not Reported
Hydroxychloroquine Phosphate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Phosphate	S		Unk	Not Reported
Elavil	S	Unknown		Not Reported
Adalimumab	S			Not Reported
Alendronate Sodium	S			Not Reported
Meloxicam	S			Not Reported
Pantoprazole	S			Not Reported
Sulfamethoxazole/Tri	S			Not Reported
Orencia	C	Unknown		Not Reported
Folic Acid	C			Not Reported
Cannabis Sativa	C	Unknown		Not Reported
Cimzia	C			Not Reported
Codeine	C	Unknown	Unk Unk, Qd	Not Reported
Dexilant	C	Unknown		Not Reported
Eltroxin	C	Unknown		Not Reported

	Plaquenil		C	Unknown			Not Reported
	Plaquenil		C	Unknown			Not Reported
	Celebrex		C	Unknown			Not Reported
	Celebrex		C	Unknown			Not Reported
	Celebrex		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	16081534	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022817		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cellcept			S	Unknown			Not Reported
	Cellcept			S				Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Penicillamine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Imuran			S				Not Reported

Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine	S				Not Reported
Hydroxychloroquine	S				Not Reported
Doxycycline	C	Unknown			Not Reported
Elavil /00002202/	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Sulfasalazine	C	Unknown			Not Reported
Tobramycin	C	Unknown			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported
Xeljanz	C	Unknown			Not Reported
Amitriptyline Hydrochloride	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	16739920	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-080375		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Milligram		Not Reported
	Leflunomide An			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	50 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	16879556	EXPEDITED (15-DAY)		HO, LT, OT	CA-ABBVIE-19K-028-2946533-00		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Poor Venous Access; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Orencia			S	Intravenous drip			Not Reported
	Orencia			S				Not Reported
	Triamcinolone Acetonide			S	Intra-articular			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported
	Immunoglobulins [Immunoglobulins Nos]			S	Intravenous (not otherwise specified)			Not Reported
	Immunoglobulins [Immunoglobulins Nos]			S				Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Immunoglobulin Human			S	Intravenous (not otherwise specified)			Not Reported
	Immunoglobulin Human			S				Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Mg/Kg		Not Reported

	Triamcinolone	S	Intra-articular		Not Reported
	Triamcinolone	S			Not Reported
	Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17216961	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-205628			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Leukopenia; Pulmonary Fibrosis	Hydroxychloroquine			S	Unknown	Unk		Sun
	Methotrexate			S	Unknown	Unk		Sun
	Minocycline			S	Unknown	Unk		Ranbaxy
	Mycophenolate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	15 Milligram, Daily		Not Reported
	Prednisone			C	Unknown	5-7 Milligram Daily		Not Reported
	Prednisone			C		15 Milligram, Daily		Not Reported
	Prednisone			C	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17216992	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201912003039			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17217255	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3214787-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Bowel Movement Irregularity; Depression; Gastric Disorder; Glaucoma; Nausea; Psoriasis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Varicella Zoster Vaccine Live			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17217356	EXPEDITED (15-DAY)		OT	IT-ALKEM LABORATORIES LIMITED-IT-ALKEM-2018-12210		3 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Partial Responder	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17217445	EXPEDITED (15-DAY)		DS, HO, OT	US-ADVANZ PHARMA-GSH201801-000272			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Bladder Catheterisation; Blood Calcium Increased; Blood Creatinine Increased; Blood Glucose Increased; Blood Iron Decreased; Blood Pressure Increased; Calcinosis; Cardiac Disorder; Cd4 Lymphocytes Decreased; Chest Pain; Condition	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Alemtuzumab			S	Intravenous drip	Unk		Not Reported
	Alemtuzumab			S		Second Cycle		Not Reported

Aggravated; Connective Tissue Inflammation; Diabetes Mellitus; Diarrhoea; Drug Monitoring Procedure Not Performed; Erythema; Fall; Fatigue; Gait Disturbance; Haemoglobin Decreased; Hand Fracture; Heart Rate Increased; Hyperparathyroidism Primary; Immunodeficiency; Infection; Joint Injury; Limb Injury; Loss Of Consciousness; Nephrolithiasis; Night Sweats; Optic Nerve Injury; Peripheral Swelling; Platelet Count Increased; Precancerous Cells Present; Pyrexia; Pyrexia; Renal Failure; Sinusitis; Skin Infection; Urinary Tract Infection; Visual Impairment; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17217547	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201912003116			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17217554	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201702-001086			Unknown	CAN

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

Alopecia; Drug Ineffective; Drug Intolerance; Dyspnoea; Eating Disorder; Fatigue; Infection; Intraocular Pressure Increased; Joint Swelling; Nausea; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Weight Decreased	Hydroxychloroquine	S	Unknown	Unk		Concordia
	Enbrel	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17217568	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-122817		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Laboratory Test Abnormal	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hyzaar			C	Unknown			Not Reported
	Venlafaxine Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17217895	EXPEDITED (15-DAY)		HO	CA-ROCHE-2505703		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue;	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17218019	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-106735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash	Ciprofloxacin			S	Unknown	Unk		Aurobindo
	Clindamycin			S	Unknown	Unk		Aurobindo
	Losartan			S	Unknown	Unk		Aurobindo
	Moxifloxacin			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enalapril			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Isoniazid			S	Unknown	Unk		Not Reported

	Keflex	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Lopresor	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Penicillin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Saccharated Iron Oxide	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Cipro	C	Unknown	Unk	Not Reported
	Hydroxyquinoline Sulfate	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17218475	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-2019SP013302		23 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Behaviour Disorder; Central Nervous System Lupus; Central Nervous System Vasculitis; Cerebral Ischaemia; Confusional State; Decorticate Posture; Depressed Level Of Consciousness; Headache; Infection; Liver Function Test Abnormal; Meningitis Enteroviral; Neck Pain; Off Label Use; Photophobia; Pyrexia; Speech Disorder; Viral Upper Respiratory Tract	Prednisolone			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	7.5 Milligram Per Day		Not Reported
	Prednisolone			S	Oral	40 Milligram		Not Reported
	Prednisolone			S	Unknown	Weaned By 5 Mg Per Week To 5 Mg Daily		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	150 Milligram		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Rituximab			S	Unknown	375 Mg/M2 In 2 Doses 14 Days Apart		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	1 G Infusion In 2 Doses 14		Not Reported

Infection; Vomiting					Days Apart	
	Hydroxychloroquine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17218566	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-3212652-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Fall; Fear Of Injection; Injection Site Warmth; Skin Reaction; Stress; Weight Increased; Wrist Fracture	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17218589	EXPEDITED (15-DAY)		OT	FR-ZYDUS-045120		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma	Atorvastatin			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Warfarin			S	Oral	()		Not Reported
	Anastrozole			S	Oral			Zydus Pharm
	Acetylsalicylate Lysine/Acetylsalicylic Acid			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17218937	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019557715			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness;	Celecoxib			S	Oral	200.0 Mg, 2x/Day		Pfizer
	Enbrel			S		Unk		Pfizer
	Rituximab			S	Intravenous drip	Unk		Not Reported

Pain	Actemra	S	Unknown	Unk		Not Reported
	Arava	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17218954	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019557947		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Celebrex			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Anakinra			S	Unknown			Not Reported
	Apo-Warfarin			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17219075	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-39439		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug	Etanercept			S	Unknown	Unknown		Not Reported

Intolerance; Drug Resistance; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Apo-Hydroxyquine	S	Unknown	Unknown	Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Plaquenil	S	Oral	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Sulfasalazine	S	Oral	Unknown	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported
	Sodium Aurothiomalate	C	Unknown	Unknown	Not Reported
	Actemra	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17220178	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2019M1127044			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness;	Synthroid			S		Unk		Mylan
	Cosentyx			S	Oral	300 Milligram, Monthly (1 Every 1 Months)		Mylan
	Diclofenac			S	Oral	Unk, Tid		Mylan
	Folic Acid			S	Unknown	Unk		Mylan

Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Golimumab	S	Unknown	Unk	Mylan
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Mylan
	Leucovorin Calcium	S	Oral	5 Milligram, Qw	Mylan
	Diltiazem Hydrochloride	S	Oral	240 Milligram	Mylan
	Meloxicam	S	Oral	7.5 Milligram, Qd	Mylan
	Methotrexate	S	Oral	25 Milligram, Qw	Mylan
	Methotrexate	S	Oral	4 Dosage Form, Qw	Mylan
	Methotrexate	S	Oral	10 Milligram, Qw	Mylan
	Otezla	S	Unknown	Unk	Mylan
	Pantoprazole	S	Oral	1 Dosage Form, Qd	Mylan
	Pantoprazole Magnesium	S	Unknown	Unk	Mylan
	Fluticasone Propionate	S		Unk	Mylan
	Mar-Pantoprazole	C	Unknown	Unk	Mylan
	Mometasone Furoate	C	Unknown	Unk	Mylan
	Premarin	C	Unknown	Unk	Mylan
	Salbutamol Sulfate	C		Unk	Mylan
	Tramadol Hydrochloride	C	Oral	Unk Unk, Qd	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17220384	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA-2019SF86740			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphonia; Arthralgia; Arthrodesis; Bursa Removal; Chest Pain; Drug Ineffective; Feeding Disorder; Hand Deformity; Magnetic Resonance Imaging Abnormal; Neck Pain; Pain In Extremity; Pain In Jaw; Product Use In Unapproved Indication; Rheumatoid Arthritis	Nexium			S	Oral			Astrazeneca
	Folic Acid			S	Unknown			Not Reported
	Gabapentin			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17220463	EXPEDITED (15-DAY)		OT	NVSC2019CA082842			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Folic Acid			S	Oral	25 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported

Humira	S	Subcutaneous	4 Mg		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Plaquenil	S	Unknown	400 Mg, Qd		Not Reported
Plaquenil	S	Unknown	400 Mg		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sarilumab	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Oral	1 G, Bid		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Topicort	S	Subcutaneous	Unk		Not Reported
Xeljanz	S	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Dec-2019	17221310	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019217423		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased	Enbrel			S	Unknown	Unk		Amgen
	Eliquis			S	Unknown	Unk, Bid		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Weekly		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2x/Day		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2x/Day		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	12316845	EXPEDITED (15-DAY)		OT	CA-ROCHE-1749593		71 YR	Female	CAN

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

Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Solution	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Celebrex	C	Unknown		Not Reported
	Cimzia	C	Subcutaneous	Solution	Not Reported
	Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	12887733	EXPEDITED (15-DAY)		OT	CA-ROCHE-1696504		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthritis; Chest Pain; Condition Aggravated; Fine Motor Skill Dysfunction; Gait Disturbance; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Ketorolac			C				Not Reported
	Naproxen			C				Not Reported
	Arthrotec			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	15422962	EXPEDITED (15-DAY)		OT	DE-ROCHE-2186283		63 YR	Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Neoral	S	Oral	Unk	Not Reported
	Neoral	S	Subcutaneous	Unk	Not Reported
	Ciclosporin	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown	Solution Subcutaneous	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Rituximab	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Xeljanz	C	Oral	5 Mg Bid	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	16210452	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020152			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown	Unk		Aurobindo
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	200 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Milligram, Once A Day		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Acetaminophen			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17176795	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201912003001			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Macular Degeneration; Pancreatitis	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	20 Mg, Bid, 20mg Die		Not Reported
	Prednisone			S	Unknown	15 Mg, Bid, 15mg Die		Not Reported
	Methotrexate			C		Ad 20mg Q Week		Not Reported

	Sulfasalazine	C	500mg Ad 200 Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17221559	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456973			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17221584	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201812-004071			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Detachment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Lansoprazole			C		Unk		Not Reported
	Lansoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17221720	EXPEDITED (15-DAY)		HO	CA-ROCHE-2456725			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy;	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	Liquid Also Know As Immune Globulin (Human)	Not Reported
	Gammagard	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Infliximab	S	Subcutaneous		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Other		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Naproxen	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17221772	EXPEDITED (15-DAY)		OT	CA-ROCHE-2505965		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis;	Actemra			S	Unknown			Not Reported

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Vomiting	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Baclofen	C	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown		Not Reported
	Estradiol	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Levaquin	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Xalatan	C	Ophthalmic	Solution	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17221795	EXPEDITED (15-DAY)		OT	CA-ROCHE-2505959		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

	Sulfate]				
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17221820	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506832			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported
	Valtrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17221822	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201912003248			Unknown	CAN

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

Drug Ineffective; Drug Intolerance; Respiratory Tract Infection; Synovitis	Hydroxychloroquine	S	Unknown	200 Mg, Bid, Tablet		Concordia
	Simponi	S	Unknown	50 Mg/ Month		Not Reported
	Xeljanz Xr	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17221825	EXPEDITED (15-DAY)		OT	CA-ROCHE-2505964		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Scar; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Cymbalta			C				Not Reported
	Hydromorphone			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17222355	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3214277-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Impaired Work Ability; Pain;	Humira			S	Subcutaneous			Not Reported

Rheumatoid Arthritis; Swelling	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17222535	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3214541-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17292381	DIRECT	N				53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Headache	Plaquenil Tab 200mg			S	Oral	Other Frequency:Other;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	15527383	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2522789-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Reaction; Deafness Transitory; Decreased Appetite; Dizziness; Ear Infection; Eating Disorder; Foot Operation; Gastrointestinal Pain; Headache; Hypophagia; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Aspirin			S	Unknown			Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Motrin			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Naprosyn			S				Not Reported
	Naprosyn			S				Not Reported
	Naprosyn			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Asa			S	Unknown	Daily Low Dose		Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported
	Plaquenil			S	Unknown			Not Reported

Vitamin C	S	Unknown		Not Reported
Diclofenac	S	Unknown		Not Reported
Diclofenac	S			Not Reported
Diclofenac	S			Not Reported
Diclofenac	S			Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Ibuprofen	S	Unknown		Not Reported
Ibuprofen	S			Not Reported
Ibuprofen	S			Not Reported
Ibuprofen	S			Not Reported
Naproxen	S	Unknown		Not Reported
Tramadol Hydrochloride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	15926362	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653493-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	15948997	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-049912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction;	Orencia			S	Unknown	125 Milligram, Qwk, 7		Bristol Myers Squibb

Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Off Label Use; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis				Months	
	Cyclosporine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tofacitinib	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Gabapentin	C	Oral	400 Milligram, Tid	Not Reported
	Tylenol Arthritis	C	Unknown	2 Tab, Qid	Not Reported
	Tylenol Arthritis	C	Unknown	650 Milligram, 4 Every 1 Day	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	15978508	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013850		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Drug	Orencia			S	Unknown	250 Mg, Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported

Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk Milligram	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Minocycline	S	Unknown		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Myochrysine	S	Intramuscular	Unk	Not Reported
	Myochrysine	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Rituxan	S	Parenteral	Unk	Not Reported
	Rituxan	S	Intravenous drip	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sirukumab	S	Unknown		Not Reported
	Ustekinumab	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Minocin	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	S	Oral	5 Milligram, Bid	Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Apremilast	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported

	Certolizumab Pegol	S	Unknown	Unk	Not Reported
	Salazopyrin	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Stelara	S	Unknown		Not Reported
	Prednisone	C	Unknown	5 Milligram	Not Reported
	Methotrexate	C	Unknown	15 Mg, Qwk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Rheumatrex [Methotrexate Sodium]	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222690	EXPEDITED (15-DAY)		OT	CA-ROCHE-2505958		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222813	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3214942-00		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Liver Injury; Loss Of Personal Independence In Daily Activities; Neck Pain; Nodule; Pain; Pain In Extremity; Swelling	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222829	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511779		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diverticulitis; Drug Ineffective; Skin Atrophy; Skin Laceration; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Cimzia			C	Subcutaneous	Solution		Not Reported
	Enbrel			C				Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported

	Humira	C	Subcutaneous	Not Reported
	Indapamide	C	Oral	Not Reported
	Naprosyn [Naproxen]	C	Unknown	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported
	Pantoloc [Pantoprazole]	C	Oral	Not Reported
	Perindopril	C	Oral	Not Reported
	Tylenol	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222836	EXPEDITED (15-DAY)		OT	CA-ROCHE-2483393			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222913	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506865			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222934	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 3.0 Month(S)		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3.0 Month(S)		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous	Therapy Duration: 3.0 Month(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 12.0 Year(S)		Not Reported
	Xeljanz			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Ciclosporin			S	Unknown			Not Reported

	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222954	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506870		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Transaminases Abnormal	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222973	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3214948-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222981	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506875			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17222998	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine		S	Oral	Not Reported
	Prednisone		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223023	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506979		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C				Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223027	EXPEDITED (15-DAY)		DS	CA-ROCHE-2508060			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223083	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-123529			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Anakinra			S	Unknown	1 Every 1 Day		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223147	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6208		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223148	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6193		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthrodesis; Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Viral Infection	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223152	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6196			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Therapeutic Product Effect	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported

Decreased; Therapeutic Product Effect Incomplete	Prevnar 13	S	Intramuscular	Not Reported
	Depo-Medrol-Lidocaine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Imuran	S	Oral	Not Reported
	Ketoprofen	S	Topical	Not Reported
	Leucovorin Calcium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223234	EXPEDITED (15-DAY)		OT	CA-ROCHE-2507989		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use, Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Cymbalta			C	Unknown			Not Reported

	Hydromorphone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223242	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506988			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Loss Of Consciousness; Malaise; Mobility Decreased	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223271	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506974		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Increased; Stomatitis; Urticaria	Humira	S	Subcutaneous	Not Reported
	Marijuana	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223307	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508009			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Cimzia			S	Unknown	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223336	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506980			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan Hycela			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen;Codeine Phosphate			C				Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223430	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506830			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Intolerance; Headache; Rheumatoid Arthritis; Tremor	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Tenofovir Disoproxil Fumarate	C			Not Reported
	Xeljanz	C			Not Reported
	Zopiclone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223434	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506983		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223445	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506833			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223629	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506837		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Nodule; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223670	EXPEDITED (15-DAY)		HO	CA-ROCHE-2506860		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo Celecoxib			S	Oral			Not Reported
	Fentanyl Matrix			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Actonel			C	Unknown			Not Reported
	Diphenoxylate Hydrochloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Loperamide Hydrochloride			C	Unknown			Not Reported
	Nasonex			C	Unknown			Not Reported
	Nasonex			C	Unknown			Not Reported

	Pantoprazole Magnesium	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Trazodone Hydrochloride	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223699	EXPEDITED (15-DAY)		OT	FR-ACCORD-168122		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma	Anastrozole			S	Oral			Accord
	Tahor			S	Oral	Strength: 10 Mg		Not Reported
	Plaquenil			S	Oral			Not Reported
	Caumadine			S	Oral			Not Reported
	Kardegic			S	Oral	Strength: 17 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223865	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508684			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17223992	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508690			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17224203	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019557766			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Celebrex			S	Oral	200 Mg, 1x/Day		Pfizer
	Arthrotec			S	Unknown	Unk		Pfizer
	Arthrotec			S	Intracardiac	Unk		Pfizer
	Levofloxacin			S	Unknown	Unk		Pfizer
	Lyrica			S	Unknown	Unk		Pfizer
	Meperidine Hcl			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Metronidazole			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Demerol			S	Unknown	Unk		Pfizer

Erythromycin	S	Unknown	Unk		Pfizer
Apo-Leflunomide	S	Unknown			Not Reported
Arava	S	Unknown	Unk		Not Reported
Bisoprolol	S	Unknown	Unk		Not Reported
Ceclor	S	Unknown	Unk		Not Reported
Erythro Base	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	400 Mg, Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Norfloxacin	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Mg, Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17224256	EXPEDITED (15-DAY)		DS	CA-PFIZER INC-2019559776			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Nervous System Injury; Stomatitis	Lyrica			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Baclofen			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Meloxicam			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17224318	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019560762			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pain	Lyrica			S	Oral	150 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Actemra			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day (Every 24 Hours)		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day (Every 24 Hours)		Not Reported
	Tylenol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17224321	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019560008			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Lyrica			S	Oral	150 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Unknown
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Tylenol [Paracetamol]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17224428	EXPEDITED (15-DAY)		OT	NVSC2019US082469		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Gait Disturbance; Herpes Zoster Disseminated; Rash	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisolone			S	Intravenous (not	Unk		Not Reported

	Cyclophosphamide			S	otherwise specified) Intravenous (not otherwise specified)	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17224878	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-3214954-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Tramacet			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Nortriptyline Hydrochloride			C				Not Reported
	Ergocalciferol			C				Not Reported
	Vagifem			C	Vaginal			Not Reported
	Tylenol			C				Not Reported
	Premarin			C		0.625 Milligram		Not Reported
	Nortriptyline			C				Not Reported
	Nortriptyline			C				Not Reported
	Methylprednisolone Acetate			C	Intramuscular			Not Reported
	Methylprednisolone Acetate			C				Not Reported

Methylprednisolone Acetate	C			Not Reported
Metformin	C			Not Reported
Lyrica	C	Oral		Not Reported
Lorazepam	C			Not Reported
Calcium	C			Not Reported
Risedronate Sodium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17225487	EXPEDITED (15-DAY)		OT	NVSC2019CA083831		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk, (Solution)		Not Reported
	Actemra			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk, (Via Int Corp Caver And Via Oral)		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Oral	Unk	Not Reported
	Plaquenil	S	Oral	1 Df, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17225491	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027777			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17225567	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019561137			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective For Unapproved Indication; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication	Lyrica			S	Oral	150 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Actemra			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Daily		Not Reported
	Leflunomide			S	Oral	20 Mg, Daily		Not Reported
	Tylenol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17225955	EXPEDITED (15-DAY)		OT	GB-BAUSCH-BL-2019-066223		23 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lupus; Central Nervous System Vasculitis; Infection; Liver Function Test Abnormal; Meningitis Enteroviral; Viral Upper Respiratory Tract Infection	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown	Weaned By 5 Mg/Week Upto 5mg/Day		Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S				Not Reported
	Prednisolone			S				Not Reported
	Rituximab			S	Unknown	2 Doses 14 Days Apart		Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown	2 Doses 14 Days Apart		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17226021	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019561366		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Enbrel			S		50 Mg, Weekly		Pfizer
	Lyrica			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Actemra			S		640 Mg, (1 Every 4 Weeks)		Not Reported
	Arava			S	Oral	Unk		Not Reported

Azathioprine	S		Unk	Not Reported
Certolizumab Pegol	S		200 Mg, (1 Every 2 Weeks)	Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Weekly	Not Reported
Gold	S		Unk	Not Reported
Humira	S	Subcutaneous	400 Mg, Weekly	Not Reported
Humira	S	Subcutaneous	40 Mg, Weekly	Not Reported
Hydroxychloroquine	S		Unk	Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Mycophenolate Mofetil	S		Unk	Not Reported
Orencia	S		Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Weekly	Not Reported
Rituximab	S		Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Piroxicam	C		Unk	Not Reported
Prednisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17226419	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019561826			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Lyrica			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Mirtazapine			S	Unknown	15 Mg, Unk		Not Reported
	Mirtazapine			S	Unknown	15 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported

	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17226648	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-109146		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Palpitations	Escitalopram			S	Oral	20 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	2 Dosage Form, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17226826	EXPEDITED (15-DAY)		DS	SK-BEH-2019106701		31 YR	Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event; Product Use In Unapproved Indication; Uterine Hypotonus	Privigen			S	Intravenous (not otherwise specified)	60 Gram, Tot		Csl Behring
	Privigen			S	Intravenous (not otherwise specified)	Unk		Csl Behring
	Bisulepin			S	Intravenous (not otherwise specified)	1 Milligram		Not Reported
	Albumin			S	Intravenous (not otherwise specified)	20 Gram, Qd		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	16 Milligram, Qd		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	4 Milligram, Qd		Not Reported
	Hydrocortisone			S	Intravenous (not otherwise specified)	400 Milligram, Qd		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	250 Milligram, Qd		Not Reported

Methylprednisolone	S	Intravenous (not otherwise specified)	250 Milligram, Qd	Not Reported
Prednisone	S	Oral	20-30 Mg/24 H	Not Reported
Prednisone	S	Oral	20-30 Mg/24 H	Not Reported
Penicillin G [Benzylpenicillin Sodium]	S	Intravenous (not otherwise specified)	5 Milliliter, Qid	Not Reported
Vulmizolin	S	Intravenous (not otherwise specified)	1 Gram, Tid	Not Reported
Cefixime	S	Oral	400 Milligram, Bid	Not Reported
Ornidazole	S	Oral	500 Milligram, Bid	Not Reported
Fluconazole	S	Oral	100 Milligram, Qd	Not Reported
Fluconazole	S	Intravenous (not otherwise specified)	100 Milligram, Qd	Not Reported
Cefotaxime	S	Intravenous (not otherwise specified)	1 Gram, Tid	Not Reported
Cefotaxime	S	Intravenous (not otherwise specified)	1 Gram, Tid	Not Reported
Metoprolol Tartrate	S	Oral	25 Milligram, Bid	Not Reported
Bisoprolol Fumarate	S	Oral	2.5 Milligram, Qd	Not Reported
Calcium Carbonate	S	Oral	500 Milligram, Bid	Not Reported
Folic Acid	S	Oral	10 Milligram, Bid	Not Reported
Potassium Chloride	S	Oral	600 Milligram, Tid	Not Reported
Vitamin D3	S	Oral	1500 International Unit, Qd	Not Reported
Vitamin B C Complex	S	Oral	Unk	Not Reported
Magnesium Lactate	S	Oral	500 Milligram, Bid	Not Reported
Vitamin K Nos	S	Intravenous (not otherwise specified)	10 Milligram, Tid	Not Reported
Etamsylate	S	Intravenous (not otherwise specified)	500 Milligram, Tid	Not Reported
Aminomethylbenzoic Acid	S	Intravenous (not otherwise specified)	50 Milligram, Tid	Not Reported
Flebogamma Dif	S	Intravenous (not	Unk	Not Reported

	[Immunoglobulin Human Normal]		otherwise specified)		
	Nadroparine	S	Subcutaneous	0.3 Milliliter, Qd	Not Reported
	Omeprazole	S	Oral	20 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram /12-24h	Not Reported
	Paracetamol	S	Oral	500 Milligram, Prn	Not Reported
	Paracetamol	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	13029297	EXPEDITED (15-DAY)		OT	CA-ROCHE-1867378		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antibody Test Positive; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	13202187	EXPEDITED (15-DAY)		OT	CA-ROCHE-1891284		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthritis; Chest Pain; Condition Aggravated; Fine Motor Skill Dysfunction; Gait Disturbance; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	13280503	EXPEDITED (15-DAY)		HO	CA-ROCHE-1848397			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous	Therapy Duration: 2.0 Month(S)		Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	14408416	NON-EXPEDITED			PR-AMGEN-USASP2018006037		71 YR	Female	PRI

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Subcutaneous	Unk		Amgen
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported

	Orencia			S	Subcutaneous	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	14911755	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-045068		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Poor Venous Access; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate	Abatacept			S	Intravenous drip	250 Mg, Qmo; For 3 Months		Bristol Myers Squibb
	Abatacept			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Intra-articular	Unk		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Actemra			S	Subcutaneous	250 Milligram, Cyclical 6 Months		Not Reported
	Adalimumab			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd 3 Years		Not Reported
	Anakinra			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qd, 3 Years		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk, For 4 Months		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Etanercept			S	Subcutaneous	25 Mg, Qwk (2 Every 1 Week)		Not Reported
	Etanercept			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	For 3 Months		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Oral	5 Milligram/Kilogram, Qd		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Immune Globulin			S	Intravenous (not	70 Gram, Herbal Tea		Not Reported

Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	(Immunoglobulins Nos)		otherwise specified)		
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	For 3 Months	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram, 5 Months	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Q6wk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk, For 9 Months	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk, For 10 Years	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Prednisone	S	Unknown	50 Milligram	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	15057803	EXPEDITED (15-DAY)		DS	CA-ROCHE-2143241		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Remicade	S	Subcutaneous		Not Reported
Xeljanz	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported
Prednisone	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	15333172	EXPEDITED (15-DAY)		OT	CA-ROCHE-2177364		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	15411594	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186708			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	15415994	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186074		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Arthralgia; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder	Rituxan			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown	5 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocin			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	4 Months		Not Reported
	Salazopyrin			S	Unknown	4 Months		Not Reported
	Simponi			S	Unknown	334		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Orencia			C	Unknown	4 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	15842981	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20151104439			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Operation; Spinal Operation; Spinal Stenosis; Treatment Failure	Tramacet			S	Unknown			Not Reported
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Metformin			C	Unknown			Not Reported
	Lorazepam			C	Unknown			Not Reported
	Nortriptyline Hydrochloride			C	Unknown			Not Reported
	Vagifem			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Vitamin D			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Tylenol Arthritis Pain			C	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported

	Methylprednisolone Acetate	C	Unknown	Not Reported
	Depomedrol	C	Intramuscular	Not Reported
	Lyrica	C	Unknown	Not Reported
	Nortriptyline	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	15934150	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656844-00		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma; Off Label Use	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Diclofenac			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	16803329	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-BEH-2019106699			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy; No Adverse	Privigen			S	Transplacental	Unk		Csl Behring
	Privigen			S	Transplacental	Unk		Csl Behring

Event; Oligohydramnios; Premature Baby	Bisulepin	S	Transplacental	Unk	Not Reported
	Albumin	S	Transplacental	Unk	Not Reported
	Dexamethasone	S	Transplacental	Unk	Not Reported
	Dexamethasone	S	Transplacental	Unk	Not Reported
	Hydrocortisone	S	Transplacental	Unk	Not Reported
	Methylprednisolone	S	Transplacental	Unk	Not Reported
	Methylprednisolone	S	Transplacental	Unk	Not Reported
	Prednisone	S	Transplacental	Unk	Not Reported
	Prednisone	S	Transplacental	Unk	Not Reported
	Penicillin G [Benzylpenicillin Sodium]	S	Transplacental	Unk	Not Reported
	Vulmizolin	S	Transplacental	Unk	Not Reported
	Cefixime	S	Transplacental	Unk	Not Reported
	Ornidazole	S	Transplacental	Unk	Not Reported
	Fluconazole	S	Transplacental	Unk	Not Reported
	Cefotaxime	S	Transplacental	Unk	Not Reported
	Cefotaxime	S	Transplacental	Unk	Not Reported
	Metoprolol Tartrate	S	Transplacental	Unk	Not Reported
	Bisoprolol Fumarate	S	Transplacental	Unk	Not Reported
	Calcium Carbonate	S	Transplacental	Unk	Not Reported
	Folic Acid	S	Transplacental	Unk	Not Reported
	Potassium Chloride	S	Transplacental	Unk	Not Reported
	Vitamin D [Colecalciferol]	S	Transplacental	Unk	Not Reported
	Vitamin B Complex	S		Unk	Not Reported
	Magnesium Lactate	S	Transplacental	Unk	Not Reported
	Vitamin K Nos	S	Transplacental	Unk	Not Reported
	Etamsylate	S	Transplacental	Unk	Not Reported
	Aminomethylbenzoic Acid	S	Transplacental	Unk	Not Reported
	Nadroparine	S	Transplacental	Unk	Not Reported
	Omeprazole	S		Unk	Not Reported

	Hydroxychloroquine	S		Unk		Not Reported
	Paracetamol	S	Transplacental	Unk		Not Reported
	Flebogamma Dif [Immunoglobulin Human Normal]	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	16826890	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1109354		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Leflunomide			S	Unknown			Barr
	Meloxicam			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17054505	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1137954		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Eliquis Film Coated			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17175535	EXPEDITED (15-DAY)		OT	NVSC2018CA000536			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Methotrexate			S	Intra-arterial	25 Mg, Qw (We)		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Qd	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk (Solution Intravenous)	Not Reported
Simponi	S	Subcutaneous	Unk (Solution Subcutaneous)	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Sulfasalazine	S	Unknown	1 G, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17178820	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA-1153374			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Off Label Use	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17182234	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2019-CA-1154329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaphylactic Shock; Blood Test Abnormal; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Otezla			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Doxepin Hydrochloride			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17202822	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019552521		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

Arava	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227103	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027775			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227186	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0019		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported

Therapeutic Product Effect Incomplete

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227209	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0005			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Arthrotec			S	Intracardiac			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Meperidine Hcl			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Erythro Base			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227368	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508664		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Rheumatoid Factor Positive; Spinal Column Injury; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Mobicox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227449	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508668		63 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227524	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508670			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Impaired Work Ability; Joint Swelling; Polyarthritis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Indometacin			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227655	EXPEDITED (15-DAY)		HO	CA-ROCHE-2508065			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Alendronate Sodium	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227859	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508706			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227866	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1162557			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Hypersensitivity Pneumonitis; Interstitial Lung Disease	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Doxycycline			C	Oral	50 Milligram Daily;		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227867	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1162512		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Off Label Use; Respiratory Tract Infection; Rheumatoid Arthritis; Sinus Disorder; Sinusitis Noninfective	Methotrexate			S	Subcutaneous	12.5 Mg, 1 Every 1 Week		Barr
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Ergocalciferol/Riboflavin/Thiamine/Vitamin A			C	Unknown			Not Reported

	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Estradiol	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	L-Thyroxine /00068001/	C	Unknown	Not Reported
	Tylenol Arthritis Pain 8h	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227952	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1162544			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Methotrexate			S	Unknown			Barr
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Desoximetasone			C	Oral			Not Reported
	Varilrix			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227953	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1162567		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Pharyngeal Oedema; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227964	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-FR2019236411		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Headache	Benlysta			S	Intravenous drip	D1-D14-D28 Then Every 4 Weeks At 10 Mg / Kg		Glaxosmithkline
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported
	Clareal			C	Unknown	Unk		Not Reported
	Cortancyl			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17227991	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1162555		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Gout; Loss Of Personal Independence In Daily Activities; Metabolic Surgery; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity;	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Simponi			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Synovitis; Weight Increased	Celebrex	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Clomipramine	C	Unknown	Not Reported
	Allopurinol	C		Not Reported
	Folic Acid	C		Not Reported
	Pantoloc	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Zyloprim	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17228205	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512613		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17228231	EXPEDITED (15-DAY)		HO	CA-ROCHE-2506976		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone	Actemra			S	Unknown			Not Reported

Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Joint Laxity; Limb Deformity; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Folic Acid	C	Subcutaneous	Not Reported
	Folic Acid	C	Subcutaneous	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17228584	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0022			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17228792	EXPEDITED (15-DAY)		OT	FR-SA-2019SA325453		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Plaquenil			S		1 Df, Qd		Sanofi
	Lovenox			S				Sanofi
	Doliprane			S				Not Reported
	Prednisone			S		1 Df, Qd		Not Reported
	Aspegic (Acetylsalicylate Lysine)			S				Not Reported
	Pentoxifylline			S		1 Df, Qd		Sanofi
	Kardegic			S				Not Reported
	Gestarelle G			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17230242	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1125335		10 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; End Stage Renal Disease; Product Use In Unapproved Indication; Proteinuria	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Unk		Mylan
	Hydroxychloroquine			S	Intravenous (not otherwise specified)	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17230243	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1164140			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug	Meloxicam			S	Oral			Teva

Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate	S	Oral			Barr
	Methotrexate	S	Oral			Barr
	Actemra	S	Subcutaneous			Not Reported
	Arava	S	Unknown	20 Milligram Daily;		Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Mobicox	S	Oral	7.5 Milligram Daily;		Not Reported
	Sulfasalazine	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17230289	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019056807			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Actinic Keratosis; Arthrodesis; Asthma; Coordination Abnormal; Dry Eye; Gastrointestinal Disorder; Nausea; Palpitations; Photosensitivity Reaction; Rash; Treatment Failure	Cimzia			S		200 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Cimzia			S		200 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Sulfasalazine			S		500 Milligram, 2x/Day (Bid)		Not Reported
	Sulfasalazine			S		1000 Milligram, 2x/Day (Bid)		Not Reported
	Methotrexate			S	Oral	Dose: 5 (Unit Not Reported)		Not Reported
	Hydroxychloroquine			S		400 Unk		Not Reported
	Hydroxychloroquine			S		200 Milligram, Once Daily (Qd)		Not Reported
	Leflunomide			S		20 Milligram, Once Daily (Qd)		Not Reported
	Leflunomide			S		10 Milligram, Once Daily (Qd)		Not Reported

	Depo-Medrol	C	Unk	Not Reported
	Pantoprazole	C	40 Milligram, Once Daily (Qd)	Not Reported
	Arava	C	10 Mg Qd (1 Od Alternating With 2 Od)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17230480	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163226			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Nausea; Neuropathy Peripheral	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17230538	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163066			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis;	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	30 Milligram Daily;		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Citalopram Hydrobromide	C	Unknown	Not Reported
	Ketoprofen	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Omeprazole	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17230880	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1162562			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Pain; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jan-2020	17230891	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1162628			Male	CAN

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

Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate	S	Subcutaneous	Barr
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	11456894	EXPEDITED (15-DAY)		OT	CA-ROCHE-1625944		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antibody Test Positive; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	13258161	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895864		62 YR	Male	CAN

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

Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	14172505	EXPEDITED (15-DAY)		OT	CA-ROCHE-2016940			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Seborrhoeic Dermatitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Qwk, Ongoing: Yes		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Oral			Not Reported

	Sulfate]				
	Folic Acid	C	Oral		Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported
	Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	14789014	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107856			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	15048757	EXPEDITED (15-DAY)		OT	CA-ROCHE-2141860		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity	Actemra			S	Unknown			Not Reported

Contracture; Nausea; Psoriasis; Pustular Psoriasis; Scar; Vomiting	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Aspirin [Acetylsalicylic Acid]	C		Not Reported
	Cymbalta	C		Not Reported
	Hydromorphone	C		Not Reported
	Synthroid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17056992	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-074171		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscular Weakness; Myalgia; Peripheral Sensorimotor Neuropathy	Atorvastatin			S	Oral	40 Milligram, Once A Day		Not Reported
	Doxycycline			S	Oral	200 Milligram, Once A Day		Not Reported
	Metronidazole			S	Oral	1500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	3 Dosage Form, Once A Day		Not Reported
	Tavanic			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Clopidogrel			C	Oral	75 Milligram, Once A Day		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	Unk		Not Reported

Fluconazole	C	Oral	200 Milligram, Once A Day		Not Reported
Lansoprazole	C	Oral	15 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233154	EXPEDITED (15-DAY)		HO	CA-ROCHE-2511724		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233158	EXPEDITED (15-DAY)		HO	CA-ROCHE-2511749			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Tachycardia; Type 2 Diabetes Mellitus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233165	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509847		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Remicade			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233169	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509586			Female	CAN

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

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233179	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509855		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

	Orencia			S	Intravenous (not otherwise specified)				Not Reported
	Leflunomide			C	Unknown				Not Reported
	Methotrexate			C	Unknown				Not Reported
	Methotrexate			C	Subcutaneous				Not Reported
	Xeljanz			C	Oral				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233191	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508660		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nephrolithiasis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral	Therapy Duration:		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	Therapy Duration: 6.0		Not Reported

								Months		
	Tylenol			S	Unknown					Not Reported
	Celebrex			C	Unknown					Not Reported
	Hydromorphone Hydrochloride			C	Unknown					Not Reported
	Meloxicam			C	Unknown					Not Reported
	Methotrexate			C	Unknown					Not Reported
	Synthroid			C	Unknown					Not Reported
	Tylenol W/Codeine No. 3			C	Unknown					Not Reported
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233192	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508100		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233199	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510977			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Erythematosus	Arava		S	Unknown		Not Reported
	Cetirizine		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Folic Acid		S	Unknown		Not Reported
	Fosamax		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole		S	Unknown		Not Reported
	Prednisone		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233201	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510372			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233221	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511034			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512674		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233230	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512706			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

Orencia	S	Unknown			Not Reported
Simponi	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Xeljanz	S	Unknown			Not Reported
Enbrel	S	Unknown			Not Reported
Cimzia	C	Unknown	Single-Use Prefilled Syringe		Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233236	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510967			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Intracavernous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Simponi		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233326	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508686			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pain	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233328	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233334	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508699		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233339	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508709		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Boric Acid			S	Unknown			Not Reported
	Disodium Edetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Phenylephrine Hcl			S	Unknown			Not Reported
	Rho D Immune Globulin			S	Unknown	Powder		Not Reported
	Sodium Borate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Tofacitinib	S	Unknown		Not Reported
	Celebrex	C	Oral		Not Reported
	Ibuprofen	C	Oral		Not Reported
	Lipitor	C	Oral		Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509589		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2020	17233345	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508677		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2020	17233657	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163213		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Anaphylactic Reaction; Contraindicated Product Administered; Drug Ineffective; Infection	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2020	17233658	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163218		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic;	Methotrexate			S	Unknown			Barr

Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Unknown		Not Reported
	Ammonium Chloride/Guaifenesin/ Sulfamethoxazole/Tri Methoprim	C	Unknown		Not Reported
	Celebrex	C	Unknown	400 Milligram Daily;	Not Reported
	Septra	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2020	17233660	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163209		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Epicondylitis; Malaise; Motor Dysfunction; Musculoskeletal Pain; Pain; Pain In Extremity; Rheumatoid Arthritis; Swelling	Methotrexate			S	Oral	20 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Oral	20 Mg, 1 Every 2 Week		Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Haemophilus Influenzae Vaccine			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

	Prevnar 13	C	Intramuscular	Not Reported
	Tetanus Vaccine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2020	17233661	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163211		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Swelling; Malaise; Nausea; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete; Unevaluable Event; Vomiting	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Unknown	25 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Acetaminophen;Codeine Phosphate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown	15 Milligram Daily;		Not Reported
	Pregabalin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Jan-2020	17233662	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163222		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	11720121	EXPEDITED (15-DAY)		DS	CA-ROCHE-1657676			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	12182291	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1723643		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Sleep Disorder; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Viral Infection	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Urethral			Not Reported
	Methotrexate Sodium			S	Oral	(2.5 Mg- 8 Tablets Orally Once Weekly)		Not Reported
	Methotrexate Sodium			S	Unknown	Solution For Injection		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Oral	Therapy Duration 24.0 Years		Not Reported
	Methotrexate			S	Oral	Therapy Duration 24.0 Years		Not Reported
	Methotrexate			S	Unknown	Solution For Injection		Not Reported
	Xeljanz			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	12913291	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092198		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Oral	100 Milligram		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous	100 Milligram		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	100 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Tocilizumab			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	30 Milligram, Qd		Not Reported
	Methotrexate			C	Oral	25 Milligram, Qwk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Cortisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	14702522	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018012689		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Contraindicated Product Administered; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2x/Day (Bid)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Weekly (Qw)		Not Reported
	Prednisone			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Gold			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	14967529	EXPEDITED (15-DAY)		OT	PHHY2018ES012236		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Maculopathy; Retinopathy; Toxicity To Various Agents	Methotrexate			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	15879970	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019001966		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction;	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported

Drug Ineffective; Dyspepsia; Gastric Disorder; General Physical Health Deterioration; Insomnia; Nausea; Rheumatoid Arthritis	Arava	S			Not Reported
	Enbrel	S		5 Months	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Minocycline	S			Not Reported
	Myochrysine	S	Intramuscular	Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Orencia	C	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	C		Solution	Not Reported
	Minocycline Hydrochloride	S			Not Reported
	Otezla	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
	Salazopyrin	S			Not Reported
	Simponi	S		Solution Subcutaneous	Not Reported
	Sirukumab	S			Not Reported
	Sulfasalazine	S			Not Reported
	Ustekinumab	S			Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	15920789	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1007712			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17109182	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1144885		80 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Allopurinol			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17180492	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1124088			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Nasopharyngitis; Oedema Peripheral; Pulmonary Hypertension	Ambrisentan			S	Unknown	Unk		Not Reported
	Ambrisentan			S	Unknown	30 Milligram, Qd		Not Reported
	Ambrisentan			S	Unknown	1 Dosage Form, Qd		Not Reported
	Omeprazole			S	Oral	2 Df, Qd (1 Df, Bid, 1-0-1)		Not Reported
	Pregabalin			S	Unknown	3 Df, Qd (1 Df, Tid 1-1-1)		Not Reported
	Ramipril			S	Oral	2 Df, Qd (1 Df, Bid 1-0-1)		Mylan
	Eliquis			S	Unknown	2 Df, Qd (1 Df, Bid1-0-1)		Mylan

	Spasmolyt	S	Unknown	1 Df (15 Unknown Unit), Qd (1-0-0)	Mylan
	Spasmolyt	S	Unknown	30 Milligram, Qd(0-0-1)	Mylan
	Quensyl	S	Unknown	2 Df, Qd (1 Df, Bid)	Mylan
	Roactemra	S	Unknown	162 Milligram, Qw	Mylan
	Volibris	S		Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17211642	EXPEDITED (15-DAY)		OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-121744		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue; Meningioma	Coumadine			S	Oral	Unk		Bristol Myers Squibb
	Tahor			S	Oral	1 Dosage Form,Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Milligram		Not Reported
	Anastrozole			S	Oral	1 Milligram, Daily		Not Reported
	Kardegic			S	Oral	1 Dosage Form, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17233785	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508127			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate			S	Unknown			Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Ramipril	S	Oral	Not Reported
	Ramipril	S	Oral	Not Reported
	Tylenol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17233788	EXPEDITED (15-DAY)		HO	FR-ACCORD-168358		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Drug Interaction; Palpitations	Escitalopram			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17233832	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508676		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Synovitis; Throat Tightness	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17233853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508248			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tylenol			S	Unknown			Not Reported
	Acetaminophen;Codeine Phosphate			C				Not Reported
	Celecoxib			C				Not Reported
	Hydromorphone Hcl			C				Not Reported

	Meloxicam	C	Not Reported
	Methotrexate	C	Not Reported
	Synthroid	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17233884	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512608			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17234000	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508679		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Factor Positive; Swelling;	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Toxicity To Various Agents; Visual Impairment	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported
	Sulfasalazine		C	Oral	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235102	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509989			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235110	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511664		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Desoximetasone	C	Unknown	Not Reported
	Orencia	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509498			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235219	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508680			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235314	EXPEDITED (15-DAY)		HO	CA-ROCHE-2511659			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508236			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235478	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510370			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235532	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508005			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported

	Xeljanz	C	Not Reported
	Acetaminophen	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235554	EXPEDITED (15-DAY)		OT	CA-ROCHE-2506836		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235586	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508702		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235588	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508691		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17235892	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508007			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Hand Deformity; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17236015	EXPEDITED (15-DAY)		OT	GB-ALKEM LABORATORIES LIMITED-GB-ALKEM-2019-11056		23 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lupus; Central Nervous System Vasculitis; Infection; Meningitis Enteroviral; Viral Upper Respiratory Tract Infection	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Azathioprine			S	Unknown	150 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	7.5 Milligram, Qd		Not Reported
	Prednisolone			S				Not Reported
	Prednisolone			S				Not Reported
	Rituximab			S	Unknown	375 Milligram/Sq. Meter		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17236298	EXPEDITED (15-DAY)		HO	CA-ROCHE-2507985		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Necrosis; Skin Ulcer	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17236303	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509500		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17236356	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019562029			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Hypertension;	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Inflammation; Joint Lock; Liver Function Test Increased; Mobility Decreased; Musculoskeletal Disorder; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Urticaria	Arava	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Desoximetasone	C		Unk		Not Reported
	Leflunomide	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17236467	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019563220			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Impaired Work Ability; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17236760	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020001489			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17237888	EXPEDITED (15-DAY)		CA, DE, OT	FR-MYLANLABS-2020M1001681			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby; Patent Ductus Arteriosus; Premature Baby; Premature Separation Of Placenta; Right-To-Left Cardiac Shunt	Esomeprazole			S	Transplacental	20 Milligram, Qd		Not Reported
	Imurel /00001501/			S	Transplacental	150 Milligram, Qd		Mylan
	Diffu K			S	Transplacental	1 Dosage Form, Once Daily (Qd)		Mylan
	Plaquenil /00072603/			S	Transplacental	400 Milligram, Once Daily (Qd)		Mylan
	Cortancyl			S	Transplacental	1 Dosage Form, Once Daily (Qd)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238309	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-40415		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Contraindicated Product Administered; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unknown, Solution Subcutaneous		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Nexium			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Suphedrine			C	Unknown			Not Reported

Trazodone	C	Unknown			Not Reported
Tylenol	C	Unknown			Not Reported
Tylenol Extra Strength	C	Unknown	Unknown		Not Reported
Valsartan	C	Unknown	Unknown		Not Reported
Wellbutrin	C	Unknown	Extended Release		Not Reported
Esomeprazole	C	Unknown			Not Reported
Lumigan Rc	C	Ophthalmic	Solution Opthalmic		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238416	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163496			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	1 Gram Daily;		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238449	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163202			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Overdose; Psoriatic Arthropathy	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

	Leflunomide	C	Unknown	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238450	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163845			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238453	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163189		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Pain In Extremity; Peripheral	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Swelling; Psoriasis	Gold		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Remicade		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238591	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163350			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Methotrexate			S	Unknown			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Imuran			S	Unknown	100 Milligram Daily;		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	100 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	66.6667 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	66.6667 Milligram Daily;		Not Reported
	Glyburide			C		750 Milligram Daily;		Not Reported
	Infliximab			C				Not Reported
	Lipitor			C		10 Milligram Daily;		Not Reported
	Metformin			C	Oral			Not Reported
	Mycophenolate Mofetil			C	Oral	1500 Milligram Daily;		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238593	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1163798			Female	CAN

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

Acute Respiratory Failure; Alopecia	Methotrexate		S	Unknown	Barr
	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe		C		Not Reported
	Leflunomide		C		Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238598	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1163175			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Ineffective	Methotrexate			S	Subcutaneous			Barr
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238601	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1162744		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238639	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1163342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Asthma; Blister; Disability; Dyspepsia; Gastric Disorder; Oral Herpes; Oropharyngeal Pain; Pain In Extremity; Peripheral Swelling	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C		25 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17238646	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163849			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17239456	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163976		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome;	Methotrexate			S	Unknown			Barr

Low Density Lipoprotein Decreased	Plaquenil		S	Unknown	Not Reported
	Salazopyrin		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17239457	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163894		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Flushing; Interstitial Lung Disease; Off Label Use	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Acetaminophen			C	Unknown	3000 Milligram Daily;		Not Reported
	Esomeprazole			C	Unknown	40 Milligram Daily;		Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Lumigan Rc			C	Ophthalmic			Not Reported
	Suphedrine [Pseudoephedrine Hydrochlroiide]			C	Unknown	10 Milligram Daily;		Not Reported
	Trazodone			C	Unknown	200 Milligram Daily;		Not Reported
	Valsartan			C	Unknown			Not Reported

	Valsartan	C	Unknown		Not Reported
	Wellbutrin Xl	C	Unknown	300 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jan-2020	17239894	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-000573		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Chest Pain; Respiratory Distress; Tachycardia; Unevaluable Event	Escitalopram			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	13965727	EXPEDITED (15-DAY)		OT	CA-SA-2017SA153945		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Spinal Column Injury; Treatment Failure	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Methotrexate Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Unknown	Unk Unk,Unk		Not Reported
	Mobicox			C	Unknown	15 Mg,Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	14128229	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020204		54 YR	Female	CAN

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

Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Leflunomide	S	Oral	20 Mg, Qd	Apotex
	Leflunomide	S	Unknown	20 Mg, Qd	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	400 Mg, Qd	Not Reported
	Methotrexate	C	Subcutaneous	17.5 Mg, Unk	Not Reported
	Methotrexate	C	Subcutaneous	15 Mg, Unk	Not Reported
	Methotrexate	C	Unknown	15 Mg, Q.Wk.	Not Reported
	Sulfasalazine	C	Oral	1 G, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	15044843	EXPEDITED (15-DAY)		DS	CA-ROCHE-2141913		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	15337341	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019544		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Leflunomide			S	Oral	Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Lipitor			S	Unknown	40 Mg, Qd		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral	300 Mg, Qd		Not Reported
	Spiriva			S	Unknown	2.5 Mg, Bid		Not Reported
	Zenhale			S	Unknown	200 Mg, Bid		Not Reported
	Zenhale			S	Unknown	400 Mg, Bid		Not Reported
	Tiotropium Bromide Monohydrate			S	Unknown	2.50 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	15411424	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186685		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Knee Arthroplasty; Limb Discomfort; Musculoskeletal Discomfort; Pain; Pharyngeal Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Penicillin G [Benzylpenicillin]	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	16044441	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1019965		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis;	Fentanyl			S	Unknown			Cephalon
	Gabapentin			S	Oral	200 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous	1 Every 1 Week .		Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2.5 Gram Daily;		Not Reported
	Apo-Gabapentin			S	Oral	200 Milligram Daily;		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported

Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Actonel	C	Unknown		Not Reported
	D-Alpha Tocopherol	C	Unknown	2400 Milligram Daily;	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown		Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram Daily;	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	80 Milligram Daily;	Not Reported
	Esomeprazole Magnesium Trihydrate	C		80 Milligram Daily;	Not Reported
	Ferrous Gluconate	C	Unknown	300 Milligram Daily;	Not Reported
	Nasonex	C	Unknown		Not Reported
	Nortriptyline Hydrochloride	C	Oral		Not Reported
	Prednisone	C	Unknown	5 Milligram Daily;	Not Reported
	Trazodone Hydrochloride	C	Oral		Not Reported
	Trazodone Hydrochloride	C		50 Milligram Daily;	Not Reported
	Tylenol	C	Oral	1000 Milligram Daily;	Not Reported
	Acetaminophen/Oxycodone Hydrochloride	C	Unknown		Not Reported
	Nexium	C	Unknown	80 Milligram Daily;	Not Reported
	Acetaminophen	C		1000 Milligram Daily;	Not Reported
	Cholecalciferol	C			Not Reported
	Ergocalciferol	C			Not Reported
	Loperamide Hydrochloride	C			Not Reported
	Oxycodone Terephthalate	C			Not Reported
	Pantoprazole Magnesium	C		40 Milligram Daily;	Not Reported
	Perphenazine	C			Not Reported
	Vitamin A Nos	C			Not Reported
	Vitamin B12 [Vitamin B12 Nos]	C			Not Reported
	Xeljanz	C			Not Reported
	Ascorbic Acid	C	Unknown		Not Reported
	Biotin	C	Unknown		Not Reported

	Nicotinamide	C	Unknown		Not Reported
	Docosahexaenoic Acid/Eicosapentaenoic Acid	C	Unknown	2400 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	16905796	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1119247		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Ibuprofen			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral	200 Milligram Daily;		Not Reported
	Apo-Ibuprofen			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17113218	NON-EXPEDITED		OT	FR-LUPIN PHARMACEUTICALS INC.-2019-07084		49 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17169953	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018240373			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Mg		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Methotrexate			S	Intra-arterial	25 Mg, We		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk (Solution Intravenous)		Not Reported
	Simponi			S	Subcutaneous	Unk, (Solution Subcutaneous)		Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

	Tofacitinib Citrate		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17239970	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509546			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Foot Operation; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240004	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509496			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240047	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510350		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240062	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510360			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During Pregnancy; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pseudoephedrine Hcl			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240090	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510377		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240102	EXPEDITED (15-DAY)		OT	GB-ROCHE-2508910		23 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Central Nervous System Lupus; Central Nervous System Vasculitis; Infection; Liver Function Test Abnormal; Meningitis Enteroviral; Viral Upper Respiratory Tract Infection	Rituximab			S	Unknown	2 Doses 14 Days Apart		Not Reported
	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S				Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240244	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510375		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Cephalexin [Cefalexin]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Rituxan	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240263	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510386			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240286	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514006		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported

Pain; Surgical Failure	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Mobicox	C	Unknown	Not Reported
	Remicade	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240300	EXPEDITED (15-DAY)		HO	CA-ROCHE-2511123		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Folic Acid			C	Subcutaneous			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240305	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510457		56 YR	Female	CAN

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

Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Pain; Pruritus; Rash; Swelling	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240306	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510878		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240490	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511744			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511665		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240515	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509567			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240541	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0050		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240543	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0030			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240552	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0056			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pain	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Lyrica			S	Oral	Strength: 150 Mg		Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240582	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511157			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240612	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510400		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240620	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510405		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240631	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509940		60 YR	Female	CAN

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

Arthralgia; Back Injury; Back Pain; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240667	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511146			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240685	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511164			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240721	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510456		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Alendronate Sodium			C				Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240743	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510832		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240798	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512986			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17240989	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510328			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241049	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514037		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported

	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241073	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510474			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241149	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026894			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Neoplasm Malignant;	Leflunomide			S	Oral	Unk		Apotex

Pneumonia; Rheumatoid Arthritis	Plaquenil /00072602/	S	Oral	Unk		Not Reported
	Methotrexate	C	Unknown	Unk		Not Reported
	Ramipril	C	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241338	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511970			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241353	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1163471		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma	Anastrozole			S	Oral	1 Mg 1 Days		Teva
	Tahor 10 Mg, Comprimé Pelliculé			S	Oral	1 Dosage Forms 1 Days		Not Reported

	Plaquenil	S	Oral	400 Mg	Not Reported
	Coumadine	S	Oral		Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose	S	Oral	1 Dosage Forms 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241408	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026895			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Malaise; Nausea; Rheumatoid Arthritis	Leflunomide			S	Oral	Unk		Apotex
	Plaquenil /00072602/			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241549	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026898			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Leflunomide			S	Oral	Unk		Apotex
	Plaquenil /00072602/			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241602	EXPEDITED (15-DAY)		OT	CA-ROCHE-1748892		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Celebrex	C	Unknown		Not Reported
	Cimzia	C	Subcutaneous		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241664	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510470		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241691	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509956			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241712	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020001495		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Unknown
	Actemra			S	Unknown	776 Mg, Unk		Not Reported
	Plaquenil S			S	Unknown	400 Mg, Unk		Not Reported
	Desoximetasone			C		Unk		Not Reported
	Orencia			C	Intravenous (not otherwise specified)	775 Mg, Monthly		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241793	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510455		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Hepatotoxicity; Treatment Failure	Tocilizumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510421		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported

Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	5.0 Years	Not Reported
	Tylenol	S	Unknown		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Celebrex	C	Oral		Not Reported
	Codeine Phosphate	C			Not Reported
	Hydromorph	C			Not Reported
	Meloxicam	C			Not Reported
	Methotrexate	C	Unknown		Not Reported
	Synthroid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241845	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510911		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Hepatotoxicity;	Tocilizumab			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Treatment Failure	Methotrexate		S	Oral	Not Reported
	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17241867	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511098		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17242165	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511669		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate		S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Desoximetasone		C		Not Reported
	Orencia		C	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17242283	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1001068		38 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Pericarditis; Product Use In Unapproved Indication	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17243323	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509525			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17243342	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509949		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17243394	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511074		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Androgenetic Alopecia; Aphthous Ulcer; Blood Pressure Increased; Blood Pressure Systolic Increased; Drug Ineffective; Heart Rate Decreased; Infusion Related Reaction; Nasopharyngitis; Stomatitis; White Blood Cell Count Decreased	Actemra			S	Intravenous (not otherwise specified)	Not Specified		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Solution For Infusion		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Solution For Infusion		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Candesartan			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported

	Rosuvastatin Calcium	C	Unknown	Not Reported
	Asa	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17243406	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1164535			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Hospitalisation; Injury; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17243494	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020US001592		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Overdose; Ventricular Tachyarrhythmia; Ventricular Tachycardia	Hydroxychloroquine			S	Unknown	36 G		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17243976	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-			Female	CAN

2020004540

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Drug Intolerance; Flushing; Headache; Hepatic Enzyme Abnormal; Neurological Symptom; Pneumonia; Rash; Weight Increased	Etanercept			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jan-2020	17244090	EXPEDITED (15-DAY)		OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000011			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Pentoxifylline			S	Unknown	1 Df, Qd		Validus
	Plaquenil /00072603/			S	Unknown	1 Df, Qd		Not Reported
	Lovenox			S	Unknown	Unk		Not Reported
	Doliprane			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	1 Df, Qd		Not Reported
	Aspegic /00002703/			S	Unknown	Unk		Not Reported
	Kardegic			S	Unknown	Unk		Not Reported
	Gestarelle G			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	11964612	EXPEDITED (15-DAY)		HO	CA-ROCHE-1700523		53 YR	Female	CAN

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

Anaphylactic Reaction; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Dyspnoea; Headache; Liver Function Test Abnormal; Liver Function Test Increased; Pharyngeal Oedema; Rash; Rheumatoid Arthritis; Swelling; Wheezing	Rituxan	S	Intravenous (not otherwise specified)	Dose: Single	Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Dose: Single	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 3 Months	Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Unknown	Therapy Duration: 2 Months	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Simponi	C			Not Reported
	Enbrel	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	13457469	EXPEDITED (15-DAY)		OT	CA-SA-2017SA067786			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Pneumonitis; Pneumothorax	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg,Bid		Not Reported
	Naproxen			C	Oral	500 Mg,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	13851389	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-069714			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Mobicox			C	Unknown	15 Milligram, Qd		Not Reported
	Rituximab			S	Unknown			Not Reported
	Remicade			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	14501692	EXPEDITED (15-DAY)		HO	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007249			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Therapeutic Product Effect	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Decreased; Treatment Failure; Weight Decreased	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Codeine	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Milligram,2every One Days	Not Reported
	Rituximab	S	Endocervical		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	14827888	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2110529		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 6.0 Month(S)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	6.0 Months		Not Reported
	Anakinra			S	Subcutaneous	3.0 Years		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	3.0 Years		Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duaration: 3months		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immune Globulin (Immunoglobulins Nos)			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Vomiting	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Other		Not Reported
	Adalimumab	S	Subcutaneous	Therapy Duration: 3.0 Months	Not Reported
	Adalimumab	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Triamcinolone Hexacetonide	C	Unknown		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	15251729	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2018M1059141		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conduction Disorder; Electrocardiogram Qt Prolonged; Hyperkalaemia; Hypokalaemia; Mental Status Changes; Overdose; Qrs Axis Abnormal; Sinus Tachycardia; Toxicity To Various Agents; Ventricular Tachyarrhythmia; Ventricular Tachycardia	Hydroxychloroquine			S	Oral	36 Gram, Total		Not Reported
	Potassium Chloride			S	Unknown	Total 200meq In First 12h...		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	15942221	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1010010		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	16742586	EXPEDITED (15-DAY)		HO, LT, OT	CA-SHIRE-CA201927387			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea;	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram		Shire
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, 1x/2wks		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, 1x/Day:Qd		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Oral	3 Milligram, 2x/Day:Bid		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, 1x/Week		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

Obesity; Prescribed Underdose; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Hydroxychloroquine	S	Oral	5 Dosage Form, 1x/Day:Qd	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, 1x/Week	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, 1x/Week	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, 1x/Day:Qd	Not Reported
	Triamcinolone	S	Intra-articular	Unk	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17003781	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-103663			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Benzalkonium Chloride;Diphenhydramine Hydrochloride;Phenylephrine Hydr			S	Unknown			Not Reported
	Boric Acid			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Disodium Edetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported

Therapy Non-Responder; Treatment Failure	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
	Phenylephrine Hydrochloride	S	Unknown		Not Reported
	Rho D Immune Globulin	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Sodium Borate	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	5 Milligram, 2 Times/Wk	Not Reported
	Tofacitinib Citrate	S	Unknown	10 Milligram, 2 Times/Wk	Not Reported
	Tofacitinib Citrate	S	Subcutaneous	5 Milligram, 2 Times/Wk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Celebrex	C	Oral	400 Milligram	Not Reported
	Ibuprofen	C	Oral	400 Milligram	Not Reported
	Lipitor	C	Oral	10 Milligram, Qd	Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17202372	EXPEDITED (15-DAY)		OT	CA-SA-2019SA353978			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Gastrointestinal Disorder; Rheumatoid Arthritis; Therapeutic Response	Leflunomide			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk [15-25 Mg Unknown]		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi

Decreased	Sulfasalazine		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	400 Mg, Unk	Sanofi
	Prednisone		C	Unknown	Unk [7 To 20 Mg Unknown]	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17219859	NON-EXPEDITED			US-SA-2019SA359498		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Hypersensitivity	Arava			S		Unk		Sanofi
	Zolpidem Tartrate			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk, Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17244861	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510478		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 411.0		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17244870	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-201912003259			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	1 Dosage Form, Qd Film-Coated Tablet		Concordia
	Lovenox			S	Unknown	Unk		Not Reported
	Doliprane			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	1 Dosage Form, Qd		Not Reported
	Aspegic [Acetylsalicylate Lysine]			S	Unknown	Unk		Not Reported
	Pentoxifylline			S	Unknown	1 Dosage Form, Qd		Not Reported
	Kardegic			S	Unknown	Unk		Not Reported
	Gestarelle G			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17244984	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0108			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Hypertension; Inflammation; Joint Lock; Liver Function Test Increased; Mobility Decreased; Musculoskeletal Disorder; Pain; Pain In Extremity;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Urticaria	Plaquenil		S	Unknown	Not Reported
	Desoximetasone		C	Unknown	Not Reported
	Leflunomide		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17244990	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0113			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Impaired Work Ability; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245044	EXPEDITED (15-DAY)		LT	CA-ROCHE-2514896			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245069	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511680		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dental Caries; Fungal Infection; Lower Respiratory Tract Infection; Lung Disorder; Malaise; Nausea; Pain; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245123	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511732			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245145	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511722		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tramadol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245175	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511755		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245189	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2509930		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245190	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511768		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Desoximetasone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245434	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-000172		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Muscle Spasms; Pain; Rheumatoid Arthritis	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Pregabalin Capsules			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Diclofenac Sodium;Misoprostol			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Misoprostol			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5.0 Milligram, Two Times		Not Reported

					A Day			
	Etanercept		S	Unknown	Unk			Not Reported
	Amitriptyline		S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245449	EXPEDITED (15-DAY)		HO	CA-ROCHE-2512660			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245485	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-000462		55 YR	Female	CAN

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

Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Pregabalin	S	Unknown	Unk	Not Reported
	Pregabalin Capsules	S	Unknown	Unk	Not Reported
	Celecoxib	S	Unknown	Unk	Aurobindo
	Celecoxib Capsules	S	Unknown	Unk	Aurobindo
	Actemra	S	Unknown	Unk	Not Reported
	Allopurinol	S	Unknown	Unk	Not Reported
	Amitriptyline	S	Unknown	Unk	Not Reported
	Amitriptyline	S	Unknown	Unk	Not Reported
	Amitriptyline	S	Unknown	Unk	Not Reported
	Perphenazine And Amitriptyline Hydrochloride	S	Unknown	Unk	Not Reported
	Perphenazine And Amitriptyline Hydrochloride	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Diclo	S	Unknown	Unk	Not Reported
	Apo-Diclofenac	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Every Week	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported

Etanercept	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Misoprostol	S	Unknown	Unk	Not Reported
Naprosyn	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Nifedipine	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	750.0 Milligram, Every Week	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Two Times A Day	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Tofacitinib	C	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5.0 Milligram, Two Times A Day	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported

	Methotrexate		S	Oral	Unk	Not Reported
	Methotrexate		S	Parenteral	Unk	Not Reported
	Methotrexate		S	Parenteral	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245509	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1165097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Large Intestine Infection	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245516	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1165168			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Pneumonia	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245517	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1165138			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245541	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1164973		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245567	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512065		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245628	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512043		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Mobicox	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245648	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163584			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Tofacitinib			S	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245650	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512672			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

				otherwise specified)	
	Mobicox		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245688	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512708		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245703	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513979		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245713	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245745	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513989			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported

	Prednisone		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Simponi		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245815	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512668		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Drug Ineffective; Hip Fracture; Intervertebral Disc Disorder; Nausea; Rheumatoid Arthritis; Stress Fracture; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	15 Mg And 20 Mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245909	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512661		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchitis; C-Reactive Protein	Actemra			S	Unknown	1.0 Dosage Forms		Not Reported

Abnormal; C-Reactive Protein Increased; Colitis; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pneumonia; Product Dose Omission; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Thyroid Disorder; Treatment Failure; Vomiting	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Baclofen	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	1.0 Dosage Forms	Not Reported
	Estradiol	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Gravol	C	Unknown		Not Reported
	Levaquin	C	Unknown		Not Reported
	Morphine	C	Unknown		Not Reported
	Zingiber Officinale	C	Unknown		Not Reported
	Potassium Chloride	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Xalatan	C	Ophthalmic		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245947	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512027		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug	Actemra			S	Unknown			Not Reported

Ineffective; Neck Pain; Neck Surgery; Spinal Column Injury; Surgical Failure	Rituxan	S	Intravenous drip	Solution Intravenous	Not Reported
	Arava	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Unknown	Powder For Solution Intravenous	Not Reported
	Mobicox	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245971	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512719			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Drug Ineffective; Mouth Ulceration; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17245972	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511769			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17246007	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512669			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Gabapentin			C				Not Reported
	Xeljanz			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17246044	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512673		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Naprosyn [Naproxen]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17246064	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512664		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17246300	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020004661			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Pulmonary Toxicity; Treatment Failure	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17246348	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020005080			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly (1 Every 1 Week)		Unknown
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day (1 Every 12 Hours)		Pfizer
	Arava			S	Oral	10 Mg, 1x/Day (1 Every 1 Day)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day (1 Every 1 Day)		Not Reported
	Naproxen			S	Oral	500 Mg, 2x/Day (1 Every 12 Hours)		Not Reported
	Prednisone			S	Oral	Unk Unk, 1x/Day (1 Every 1 Day)		Not Reported
	Prednisone			S	Subcutaneous	1.5 Mg, 1x/Day (1 Every 1 Day)		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Monthly (1 Every 1 Month)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17246360	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020006788			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neuropathy Peripheral	Ibuprofen			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Leflunomide			S	Oral	20 Mg, Daily		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17246564	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511565		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Gold			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17246962	EXPEDITED (15-DAY)		HO	CA-ROCHE-2514284		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Nasonex	C		Not Reported
	Prednisone	C		Not Reported
	Trazodone	C		Not Reported
	Tylenol	C		Not Reported
	Zoledronic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17247295	EXPEDITED (15-DAY)		OT	CA-SA-2020SA001532			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Hydroxychloroquine			S		400 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Rosuvastatin			C		Unk		Not Reported
	Bisoprolol Sandoz			C		Unk		Not Reported
	Jamp Calcium			C		Unk		Not Reported
	Teva Risedronate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17247679	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514008			Female	CAN

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

Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248175	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1164824			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Aggression; Alopecia; Asthenia; Blood Creatinine Increased; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder; Malaise; Peripheral Swelling; Retinopathy; Sinus Disorder; Sinusitis; Synovitis; Tachyphylaxis; Urinary Tract Infection	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prolia Pre-Filled Syringe. Preservative-Free			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248198	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1165208		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Cannabis Sativa			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248417	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-001028		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported

Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Oxycodone	S	Unknown	10 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported

Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Xeljanz	S	Oral	1 Dosage Form, Q12h		Not Reported
Lyrica	C	Unknown			Not Reported
Rituximab	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248461	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1163861		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthralgia; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Darifenacin			C	Unknown			Not Reported

Desoximetasone	C	Oral	Not Reported
Dilaudid	C	Unknown	Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Not Reported
Lasix [Furosemide]	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoloc[Pantoprazole]	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Rituximab	C	Intravenous (not otherwise specified)	Not Reported
Synthroid	C	Unknown	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248462	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1164590		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal	Methotrexate			S	Unknown			Barr
	Anakinra			S	Unknown			Not Reported

Stiffness; Therapeutic Product Effect Incomplete	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248463	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1164432		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Hepatotoxicity; Interstitial Lung Disease; Off Label Use	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S				Barr
	Enbrel			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248472	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1164434		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Off Label Use; Rheumatoid Arthritis; Synovitis; Underdose; Vomiting	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248772	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1165217		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Neoplasm; Injection Site Reaction; Psoriasis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17248791	EXPEDITED (15-DAY)		OT	CA-SA-2019SA355104			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Hepatitis Acute; Hypersensitivity; Oedema; Skin Plaque; Urticaria	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S		15 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Sanofi
	Humira			S		Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jan-2020	17249211	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020004595			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity; Pulmonary Toxicity	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 1 Every 12 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	13250722	EXPEDITED (15-DAY)		OT	CA-ROCHE-1894453		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown	Cyclical		Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Therapy Duration: 9 Months		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 4 Years Cyclical		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Imuran [Azathioprine]	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years Cyclical	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Cyclosporine	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	13519793	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038272		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Mg, Unk		Not Reported
	Arava			S	Oral	10 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	400 Mg, Unk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide [Indapamide]			C	Unknown			Not Reported

Metformin	C	Unknown		Not Reported
Naproxen	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Ramipril	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	15651367	NON-EXPEDITED		OT	US-SA-2018SA038094			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Paraesthesia; Rash; Rash; Rheumatoid Arthritis; Swelling Of Eyelid	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Unknown	Unk Unk,Unk		Not Reported
	Simponi			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S				Not Reported
	Actemra			S		Unk		Not Reported
	Rituxan			S		Unk		Not Reported
	Xeljanz			C	Oral	11 Mg,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	16185568	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP011109			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease;	Azathioprine			S	Unknown	Unk, Unknown		Apotex
	Azathioprine			S	Unknown	Unk Unk, Unknown		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk, Unknown		Apotex

Pruritus; Treatment Failure	Hydroxychloroquine	S	Oral	400 Mg, Qd	Apotex
	Esomeprazole	S	Unknown	Unk	Apotex
	Folic Acid	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	162 Mg, Q.Wk.	Not Reported
	Actemra	S	Subcutaneous	162 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Sarilumab	S	Subcutaneous	20 Mg, One Every Two Weeks	Not Reported
	Sarilumab	S	Unknown	20 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Nicotinamide	S	Unknown	Unk	Not Reported
	Thiamine Hydrochloride	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	0.5 Mg, Bid	Not Reported
	Esomeprazole Sodium	S	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	400 Mg, Qd	Not Reported
	Magnesium	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	Unk	Not Reported
	Nexium /01479302/	C	Unknown	Unk	Not Reported
	Dexpanthenol	C	Unknown	Unk	Not Reported
	Riboflavin	C	Unknown	Unk	Not Reported
	Vitamin A /00056001/	C	Unknown	Unk	Not Reported
	Vitamin C /00008001/	C	Unknown	Unk	Not Reported
	Adalimumab	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	16671603	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-077101		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris			S	Intravenous (not otherwise specified)			Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Oxycodone	S	Unknown	10 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Unknown		Not Reported
Cannabis Sativa	S	Unknown		Not Reported
Minocycline	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Rituximab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	16835922	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1110159		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Cephalexin			S	Unknown			Not Reported
Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough;	Cephalexin			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Teva

Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Ciprofloxacin	S	Unknown		Not Reported
	Clindamycin Hydrochloride	S	Unknown		Actavis
	Codeine	S	Unknown		Not Reported
	Enalapril Maleate	S	Unknown		Teva
	Hctz	S	Unknown		Ivax
	Hctz	S	Unknown		Ivax
	Losartan Potassium	S	Unknown		Teva
	Methotrexate	S	Subcutaneous		Barr
	Metoprolol Tartrate	S	Unknown		Not Reported
	Moxifloxacin Hydrochloride	S	Unknown		Teva
	Penicillin G	S	Unknown		Teva
	Arava	S	Unknown		Not Reported
	Biaxin	S	Unknown		Not Reported
	Biaxin	S	Intravenous (not otherwise specified)		Not Reported
	Celebrex	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Hydralazine Hydrochloride	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Levaquin	S	Unknown		Not Reported
	Pariet	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate	S	Unknown		Not Reported
	Cipro[Ciprofloxacin]	C			Not Reported
	Esomeprazole	C			Not Reported
	Gold	C			Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported
	Iron Sucrose	C			Not Reported
	Prednisone	C	Unknown	8.5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17075620	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP025078			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Azathioprine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Mycophenolate Mofetil			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	640 Mg, Unk (1 Every 4 Weeks)		Not Reported
	Actemra			S	Unknown	640 Mg, Q.Wk.		Not Reported
	Actemra			S	Unknown	640 Mg, Unk		Not Reported
	Arava			S	Oral	Unk, Q.Wk.		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Q.O.Wk.		Not Reported
	Certolizumab Pegol			S	Unknown	200 Mg, Q.O.Wk.		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Piroxicam	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250075	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516466			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Tocilizumab			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250077	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517539			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250084	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0137			Female	CAN

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

Abdominal Discomfort; Drug Ineffective; Drug Intolerance; Flushing; Headache; Hepatic Enzyme Abnormal; Neurological Symptom; Pneumonia; Rash; Weight Increased	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250121	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516277		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250167	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514031			Female	CAN

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

Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra		S	Unknown		Not Reported
	Arava		S	Oral		Not Reported
	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Methotrexate		S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral		Not Reported
	Folic Acid		C	Unknown		Not Reported
	Leflunomide		C	Unknown		Not Reported
	Orencia		C	Unknown		Not Reported
	Tofacitinib Citrate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250187	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513966		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Pneumonia; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syring, Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

	Sodium Aurothiomalate		S	Unknown	Not Reported
	Cefalexin		C		Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250254	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020004653		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastrointestinal Disorder; Headache; Hepatic Enzyme Abnormal; Neurological Symptom; Pneumonia; Rash; Weight Increased	Methotrexate Sodium			S	Unknown			Pfizer
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown	10 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250391	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP026966		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Bone Density Decreased; Cataract; Cellulitis; Contusion; Drug Ineffective; Fatigue; Glucose Tolerance Impaired; Herpes Zoster; Hyperlipidaemia; Hypertension; Impaired Quality Of Life; Impaired Work Ability; Infection Susceptibility Increased; Inhibitory Drug Interaction; Insomnia; Oral Herpes; Poor Quality Sleep; Purpura; Skin Disorder; Weight Increased	Prednisone			S	Unknown	95 Mg, Qd		Not Reported
	Prednisone			S	Unknown	85 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk Unk, Qd, 9 To 10 Mg		Not Reported
	Prednisone			S	Unknown	Unk Unk, Qd, 10 To 12 Mg		Not Reported
	Prednisone			S	Unknown	13 Mg, Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Apotex
	Lithium Carbonate			S	Unknown	Unk		Apotex
	Memantine			S	Unknown	Unk		Apotex
	Clonidine			S	Unknown	Unk		Apotex
	Mycophenolate			S	Unknown	Unk		Apotex
	Montelukast			S	Unknown	Unk		Apotex

Cimetidine	S	Unknown	Unk	Apotex
Amlodipine	S	Unknown	Unk	Apotex
Pregabalin	S	Unknown	Unk	Apotex
Diltiazem	S	Unknown	Unk	Apotex
Hydroxychloroquine	S	Unknown	Unk	Apotex
Naltrexone	S	Unknown	4.5 Mg, Qd	Apotex
Pentoxifylline	S	Unknown	Unk	Apotex
Calcitonin	C	Unknown	Unk	Not Reported
Ketamine	S	Oral	Unk	Not Reported
Ketamine	S	Topical	Unk	Not Reported
Ketamine	S	Intravenous (not otherwise specified)	Unk	Not Reported
Lidocaine	S	Intravenous (not otherwise specified)	Unk	Not Reported
Lidocaine	S	Topical	Unk	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Ibudilast	S	Unknown	Unk	Not Reported
Mexiletine	S	Unknown	Unk	Not Reported
Metprolol	S	Unknown	Unk	Not Reported
Magnesium	S	Unknown	Unk	Not Reported
Magnesium	S			Not Reported
Vitamin B2 /00154901/	S	Unknown	Unk	Not Reported
Vitamin B2 /00154901/	S			Not Reported
Capsaicin	S	Topical	Unk	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Palmitoylethanolamide	S	Unknown	Unk	Not Reported
Spironolactone	S	Unknown	Unk	Not Reported
Vitamin C /00008001/	S	Unknown	Unk (High Dose)	Not Reported
N-Acetylcysteine	S	Unknown	Unk	Not Reported

	Bumetanide		S	Unknown	Unk	Not Reported
	Trazodone		C	Unknown	Unk	Not Reported
	Ezetimibe		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250433	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514003		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250524	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513886			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

			otherwise specified)		
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17250742	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514001		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17251204	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514002		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Unknown	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Hydroxychloroquine Sulfate		S	Oral	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Prednisone Acetate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib Citrate		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17251488	EXPEDITED (15-DAY)		HO	CA-ROCHE-2511663		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			C	Oral			Not Reported

	Orencia	C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17251490	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514005		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rotator Cuff Syndrome; Swelling; Tongue Ulceration; Tooth Infection	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Indometacin			C				Not Reported
	Prednisone			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17251781	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1165582		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling;	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported

Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Anakinra	C	Unknown	Not Reported
	Ativan	C	Unknown	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
	Omnaris	C	Unknown	Not Reported
	Oxyneo	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Restasis	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Trimethoprim	C	Unknown	Not Reported
	Urispas	C	Unknown	Not Reported
	Vagifem	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Darifenacin	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Diphenhydramine	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Kadian	C	Unknown	Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown	Not Reported
	Loperamide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17251783	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512563		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Gabapentin			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17251931	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512671		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anticipatory	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported

Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Enbrel	S	Subcutaneous	Duration 3 Years	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Duration 2 Months	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Duration 9 Years	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Duration 3.0 Months	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous Duration 12.0 Months	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous Duration 3.0 Years	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral	Duration 3.0 Months	Not Reported
	Xeljanz	S	Oral	Duration 2.0 Months	Not Reported
	Acetaminophen	C			Not Reported
	Cortisone	C			Not Reported
	Dexamethasone	C			Not Reported
	Gabapentin	C			Not Reported
	Reactine [Cetirizine Hydrochloride]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17251936	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512675		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Baclofen			C				Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C				Not Reported
	Estradiol			C				Not Reported
	Furosemide			C				Not Reported
	Levaquin			C				Not Reported
	Valsartan			C				Not Reported
	Xalatan			C	Ophthalmic			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17251947	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513965		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Orencia		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Anakinra		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17252075	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Mobicox			S	Oral			Boehringer Ingelheim
	Methotrexate			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17252322	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514897			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Decreased	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17252555	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020003020		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Etanercept			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Infliximab			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, Daily		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	9 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Daily		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Daily		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Plaquenil S	S	Unknown	200 Mg, Daily	Not Reported
	Prednisone	S	Unknown	9 Mg, Daily	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Acetaminophen	C			Not Reported
	Cortisone [Hydrocortisone]	C			Not Reported
	Dexamethasone	C			Not Reported
	Gabapentin	C			Not Reported
	Reactine [Cetirizine Hydrochloride]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17253190	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17253512	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1165601		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Potassium Chloride			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17253532	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-TEVA-2020-CA-1165259			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Ilaris Single-Use Vial	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17253796	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1165576		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Infection	Indometacin	C	Not Reported
	Prednisone	C	Not Reported
	Tramadol	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17255036	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-000256		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown	1 Dosage Form, Qd		Not Reported
	Methotrexate			S	Unknown	Unk, Qwk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2 Gram, Qd		Not Reported
	Tramacet			S	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lorazepam			C	Unknown	1 Milligram, Qd		Not Reported
	Lyrica			C	Oral	150 Milligram, Bid		Not Reported

Metformin	C	Unknown	500 Milligram, Bid		Not Reported
Metformin	C	Unknown	5 Milligram, Qd		Not Reported
Methylprednisolone Acetate	C	Intramuscular	40 Milligram, Qmo		Not Reported
Methylprednisolone Acetate	C	Subcutaneous	Unk, Qmo		Not Reported
Methylprednisolone Acetate	C	Unknown			Not Reported
Nortriptyline	C	Unknown	Unk		Not Reported
Nortriptyline	C	Unknown			Not Reported
Nortriptyline Hydrochloride	C	Unknown	20 Milligram, Qd		Not Reported
Premarin	C	Unknown	0.625 Milligram		Not Reported
Risedronate Sodium	C	Unknown	35 Milligram, Qwk		Not Reported
Tylenol	C	Unknown			Not Reported
Vagifem	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2020	17255133	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-40661			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Liver Function Test Increased; Nausea; Product Label Confusion; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Etanercept			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported

Simponi	S	Subcutaneous	Unknown		Not Reported
Tocilizumab	S	Unknown			Not Reported
Azathioprine Sodium	C	Unknown	Unknown		Not Reported
Cimzia	C	Subcutaneous	Unknown, Solution Single Use Pre-Filled Syringe		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	13246787	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895135		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Pharyngeal Oedema; Poor Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 3.0 Year(S)		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 4.0 Month(S)		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 4.0 Month(S)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 11.0 Month(S)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 11.0 Month(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	15461181	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190731			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug	Actemra			S	Unknown			Not Reported

Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Pain; Product Dose Omission; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tooth Infection; Weight Decreased	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	16387997	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-029784		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Hypersensitivity; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Celecoxib Capsules			S	Oral	200 Milligram, Once A Day		Aurobindo
	Levofloxacin Tablet			S	Unknown	Unk		Aurobindo
	Metronidazole			S	Intravenous (not otherwise specified)	5 Milligram		Aurobindo
	Pregabalin Capsules			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram, Once A Day		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported

	Humira	S	Subcutaneous	400 Milligram	Not Reported
	Leflunomide Sandoz	S	Unknown	Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Meperidine Hydrochloride	S	Unknown	Unk	Not Reported
	Meperidine Hydrochloride	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Every Week	Not Reported
	Norfloxacin	S	Unknown	400 Milligram	Not Reported
	Norfloxacin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	400 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Bisoprolol	S	Unknown	Unk	Not Reported
	Erythro Base	S	Unknown	Unk	Not Reported
	Act Diclo Miso	S	Unknown	Unk	Not Reported
	Apo-Bisoprolol	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Metronidazole	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17249853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511614		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Lyrica	C		Not Reported
	Marijuana	C		Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported
	Oxycodone	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17255236	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201709-005265			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Spinal Column Injury; Treatment Failure	Hydroxychloroquine			S	Oral	Unk		Concordia
	Arava			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg		Not Reported
	Mobicox			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17255240	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512994			Female	CAN

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

Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Aluminum Acetate	C	Unknown	Not Reported
	Atacand	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Hydrodiuril	C	Unknown	Not Reported
	Neurontin	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Benzethonium Chloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17255276	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Arthritis; Systemic Lupus Erythematosus	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17255355	EXPEDITED (15-DAY)		OT	CA-ROCHE-2511650		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Fosamax			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrocortisone Acetate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral	11.0 Years	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	11.0 Months	Not Reported
	Paracetamol	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	365.0	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Topicort [Desoximetasone]	S	Other		Not Reported
	Topicort [Desoximetasone]	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Pseudoephedrine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported

	Desoximetasone	S	Unknown		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C			Not Reported
	Salazopyrin	C			Not Reported
	Tofacitinib Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17255553	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0171			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neuropathy Peripheral	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17255583	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0180			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported

	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Naproxen	S	Oral	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17255586	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0175			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Pulmonary Toxicity; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17255899	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516117			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

					otherwise specified)					
	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17256065	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512850		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Triamcinolone Hexacetonide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17256371	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Therapeutic Product Effect Incomplete	Mobicox			S	Unknown			Boehringer Ingelheim
	Desoximetasone			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Rabeprazole	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17256772	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA006430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Plaquenil			S	Unknown	400.0 Mg, Qd		Sanofi
	Sulfasalazine			S	Unknown	2.0 G, Qd		Not Reported
	Leflunomide			S	Unknown	20.0 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	20.0 Mg, Qw		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17257640	EXPEDITED (15-DAY)		DE, HO	CN-PFIZER INC-2019529537		10 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Emphysema; Pneumothorax; Respiratory Failure	Methylprednisolone			S		20 Mg/Kg, Daily		Pfizer
	Methylprednisolone			S	Oral	1.5 Mg/Kg, Daily		Pfizer
	Methylprednisolone			S		20 Mg/Kg, Daily		Pfizer
	Immunoglobulin Human Normal			S	Intravenous (not otherwise specified)	Unk(1.5 G/Kg)		Not Reported
	Immunoglobulin Human Normal			S	Intravenous (not otherwise specified)	Unk(1.5 G/Kg), Given Again		Not Reported

	Cyclophosphamide	S	800 Mg/M2, Unk(Once As Pulse Therapy)		Not Reported
	Cyclophosphamide	S	800 Mg/M2, Unk(Once As Pulse Therapy)Given Again		Not Reported
	Cyclophosphamide	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unk		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17258069	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020006663			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Intolerance; Interstitial Lung Disease; Pulmonary Mass; Sinusitis; Synovitis; Treatment Failure	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17258667	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513921			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Other			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17258769	EXPEDITED (15-DAY)		HO	CA-ROCHE-2514032		4 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259008	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516331		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259010	EXPEDITED (15-DAY)		HO	CA-ROCHE-2514924		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported

	Xeljanz	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259029	EXPEDITED (15-DAY)		HO	CA-ROCHE-2514965		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular	Solution Intramuscular		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Varicella-Zoster Immune Globulin			S	Intramuscular	Liquid Intramuscular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259035	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514945		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Humira			S	Subcutaneous				Not Reported
	Methotrexate			S	Unknown				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259074	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516351			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259075	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516512			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259076	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514951		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rho D Immune Globulin			S	Unknown			Not Reported
	Celebrex			C	Oral			Not Reported
	Ibuprofen			C				Not Reported
	Lipitor			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259084	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516522			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259113	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516344		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Leukopenia; Peripheral Swelling; Pneumonia Viral; Stomatitis; Swelling; Synovitis; Tenderness	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported

Arava	C	Unknown	Not Reported
Darifenacin	C	Unknown	Not Reported
Desoximetasone	C	Oral	Not Reported
Dilaudid	C	Unknown	Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Vagifem	C	Vaginal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259114	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516556			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259119	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516942		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259151	EXPEDITED (15-DAY)		HO	CA-ROCHE-2517059		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported

Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Fentanyl Matrix	S	Unknown		Not Reported
	Gabapentin	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Oxycontin	S	Unknown	Tablet (Extended Release)	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Actonel	C	Unknown		Not Reported
	Diphenoxylate Hcl	C			Not Reported
	Ergocalciferol	C			Not Reported
	Esomeprazole	C			Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Loperamide	C			Not Reported
	Nasonex	C			Not Reported
	Oxycodone	C			Not Reported
	Pantoprazole	C			Not Reported
	Prednisone	C			Not Reported
	Trazodone	C	Unknown		Not Reported
	Tylenol	C			Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259162	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517578		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259163	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517516		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259171	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517542			Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259206	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517598		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259286	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517603			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259394	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518182			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2020	17259408	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518767		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Marijuana			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	14467684	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Abatacept			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	25 Mg, Unk	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported
	Simponi	C	Subcutaneous	50 Mg, One Every One Month	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	15433577	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189361			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Bacitracin			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Neomycin Sulfate			S	Unknown			Not Reported
	Polymyxin B Sulfate			S	Unknown			Not Reported
	Prednisone			C	Intramuscular			Not Reported
	Prednisone			C	Intramuscular			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	17259819	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514963		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Actemra			S	Subcutaneous			Not Reported

Administered; Drug Ineffective; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	17259832	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513906		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported

	Naproxen	C	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	17259841	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2514039		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution For Infusion		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Subcutaneous	Single Use Vial: Powder For Solution Subcutaneous		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Remicade	S	Unknown	Solution For Infusion	Not Reported
	Remicade	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Urelumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	17259873	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516209			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoporosis	Mycophenolate Mofetil			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	17259883	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518735			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Sulfasalazine		S	Unknown	Not Reported
Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	17259884	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518729		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	17259930	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516317		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jan-2020	17259983	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514063			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2020	17260299	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516104			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous bolus	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2020	17260300	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516095			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2020	17260301	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516323		23 YR	Female	CAN

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

Drug Ineffective; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2020	17260306	EXPEDITED (15-DAY)		HO	CA-ROCHE-2515464		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Pyrexia; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Folic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2020	17260308	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517545		52 YR	Female	CAN

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

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Asa	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Lantus	C	Subcutaneous	Not Reported
	Lozide [Indapamide]	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Naprosyn [Naproxen]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2020	17260314	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518102		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Humira	C	Subcutaneous	Not Reported
	Celebrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Jan-2020	17260315	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516342		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported

	Methotrexate	C	Unknown	Not Reported
	Prednisolone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	12321013	EXPEDITED (15-DAY)		OT	CA-ROCHE-1745426		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Knee Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Prednisone		S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Cetirizine Hydrochloride		S	Unknown	Not Reported
	Cortisone Acetate		S	Unknown	Not Reported
	Desoximetasone		S	Oral	Not Reported
	Desoximetasone		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride		S	Unknown	Not Reported
	Acetaminophen		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	13133034	EXPEDITED (15-DAY)		OT	CA-ROCHE-1882218		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	15719920	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthritis; Chest Pain; Drug Ineffective; Fibromyalgia; Hla Marker Study Positive; Immunodeficiency; Kyphoscoliosis; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Plantar Fasciitis; Somnolence; Spinal Osteoarthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Mobicox			S	Unknown			Boehringer Ingelheim
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	16213099	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019155494		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	2 G, Daily		Pfizer
	Hydroxychloroquine			S		400 Mg, Daily (Die)		Not Reported
	Hydroxychloroquine			S		400 Mg, Daily (Die)		Not Reported
	Actemra			S		Unk		Not Reported
	Orencia			S		125 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	16341561	EXPEDITED (15-DAY)		DS, HO, OT	CA-AUROBINDO-AUR-		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Pantoprazole			S	Oral	Unk		Aurobindo
	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Lisinopril			S	Unknown	Unk		Aurobindo
	Lisinopril			S	Unknown	Unk		Aurobindo
	Tecta			S	Oral	Unk		Not Reported
	Diclofenac			S	Oral	75 Milligram, As Required		Not Reported
	Diclofenac			S	Oral	75 Milligram, Two Times A Day		Not Reported
	Diclofenac			S	Oral	1 Dosage Form		Not Reported
	Diclofenac			S	Oral	2 Dosage Form, Once A Day		Not Reported
	Diclofenac			S	Oral	75 Milligram, Two Times A Day		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	200 Milligram, Once A Day		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Two Times A Day		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	2 Gram, Once A Day		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported

Xeljanz	S	Oral	2 Dosage Form, Once A Day	Not Reported
Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
Voltaren Sr	S	Oral	75 Milligram, Two Times A Day	Not Reported
Voltaren Sr	S	Oral	Unk	Not Reported
Voltaren Sr	S	Unknown	Unk	Not Reported
Cambia	S	Oral	2 Dosage Form, Once A Day	Not Reported
Cambia	S	Oral	1 Dosage Form	Not Reported
Cambia	S	Oral	75 Milligram, Two Times A Day	Not Reported
Plaquenil	S	Oral	1 Dosage Form, Once A Day	Not Reported
Plaquenil	S	Oral	200 Milligram, Once A Day	Not Reported
Plaquenil	S	Oral	400 Milligram, Once A Day	Not Reported
Methotrexate	S	Subcutaneous	1 Dosage Form, Every Week	Not Reported
Sulfasalazine	S	Oral	1 Gram, Two Times A Day	Not Reported
Apo-Lisinopril	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Depo-Medrol	C	Intramuscular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	16437198	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-031295		58 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Aneurysm; Drug Ineffective; Drug Resistance; Hiccups; Retinal Toxicity	Amoxicillin			S	Unknown	3 Gram, Once A Day		Aurobindo
	Amoxicillin			S				Aurobindo
	Clarithromycin			S	Unknown	1 Gram, Once A Day		Aurobindo

Doxycycline	S	Unknown	200 Milligram, Once A Day		Not Reported
Hydroxychloroquine	S	Unknown	600 Milligram, Once A Day		Not Reported
Levofloxacin	S	Unknown	500 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260543	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202001000130			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Osteoporosis	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Hydroxychloroquine			S				Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260565	EXPEDITED (15-DAY)		OT	CA-SA-2020SA006274			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatotoxicity; Rheumatoid Arthritis; Synovitis	Leflunomide			S	Oral	Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qow		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Unk		Sanofi
	Methotrexate			C	Oral	20 Mg, Qw		Not Reported
	Tocilizumab			C	Subcutaneous	162 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260591	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512569		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	4.0 Years		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	4.0 Years		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Intravenous (not otherwise specified)			Not Reported
	Imuran [Azathioprine]			S	Intravenous (not			Not Reported

			otherwise specified)	
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260649	EXPEDITED (15-DAY)		OT	CA-ROCHE-2515349		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260663	EXPEDITED (15-DAY)		OT	CA-SA-2020SA006346			Female	CAN

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

Joint Swelling; Rheumatoid Arthritis	Leflunomide		S	Oral	Unk Unk, Unk	Sanofi
	Plaquenil		S	Oral	Unk Unk, Unk	Sanofi
	Humira		C	Unknown	Unk	Not Reported
	Methotrexate		C	Unknown	Unk	Not Reported
	Simponi		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260698	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514042			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Codeine			C				Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260722	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517574			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260727	EXPEDITED (15-DAY)		OT	CA-ROCHE-2515953		49 YR	Female	CAN

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

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Actemra	S	Subcutaneous		Not Reported
	Rituximab	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Penicillin-G	S	Unknown		Not Reported
	Penicillin G [Benzylpenicillin]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Calcium	C			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260783	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514954		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported

	Darifenacin	C			Not Reported
	Desoximetasone	C			Not Reported
	Dilaudid	C			Not Reported
	Diphenhydramine	C			Not Reported
	Loperamide	C			Not Reported
	Norflex [Orphenadrine Citrate]	C			Not Reported
	Omnaris	C	Unknown		Not Reported
	Pantoprazole Sodium Anhydrous	C			Not Reported
	Plantago Ovata	C			Not Reported
	Synthroid	C			Not Reported
	Vagifem	C	Unknown	Vaginal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260826	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0247			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Toxicity; Pulmonary Toxicity	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260830	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0258		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastrointestinal Disorder; Headache; Hepatic Enzyme Abnormal; Neurological Symptom; Pneumonia; Rash; Weight Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260875	EXPEDITED (15-DAY)		OT	CA-SA-2020SA006451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neutropenia; Treatment Failure; Vasculitis; Vomiting	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Unk		Sanofi
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Cimzia			S	Subcutaneous	Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260877	EXPEDITED (15-DAY)		OT	CA-SA-2020SA006420			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Doxycycline			S	Unknown	50 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Rituximab			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported
	Simponi			C	Subcutaneous			Not Reported

	Methotrexate			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260884	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA006562		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C		5 Mg, Qd		Not Reported
	Prednisone			C		10 Mg		Not Reported
	Remicade			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17260962	EXPEDITED (15-DAY)		DS	CA-ROCHE-2513955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Limb Deformity; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Neck Deformity; Neck Mass; Pain	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Indocid [Indometacin]	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Cymbalta	C	Oral	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17261050	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514891		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling; Pneumonia; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

	Sulfate]				
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Cephalexin [Cefalexin]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17261059	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514953		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Calcium			C				Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17261070	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514041			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution For Injection		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17261091	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513945		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Shoulder Operation; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

Tiaprofenic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17262523	EXPEDITED (15-DAY)		DE, HO, OT	US-BAYER-2020-004172		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Circulatory Collapse; Dyspnoea; Hypotension; Mouth Haemorrhage; Oral Mucosal Discolouration; Oxygen Saturation Decreased; Toxicity To Various Agents	Naproxen Sodium (<= 220 Mg)			S	Oral	Unk		Bayer
	Hydroxychloroquine			S		6 G, Once		Not Reported
	Ibuprofen			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17262610	EXPEDITED (15-DAY)		OT	PHHY2019GR210755		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Ramipril			S	Unknown			Not Reported
	Ramipril			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Lansoprazole			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Not Reported
	Thyroxin			S	Oral	Unk		Not Reported
	Dicumarol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17262769	EXPEDITED (15-DAY)		OT	NVSC2020DE004106			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Ramipril			S	Oral	2 Df, Qd (1 - 0 - 1)		Not Reported
	Ramipril			S	Unknown	5 Mg, Qd		Not Reported
	Pregabalin			S	Unknown	3 Df, Qd (1 - 1- 1)		Not Reported
	Omeprazole			S	Oral	2 Df, Qd (1 - 0 - 1)		Novartis
	Omeprazole			S	Unknown	40 Mg, Qd		Novartis
	Sildenafil			S	Unknown	60 Mg, Qd		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd		Not Reported
	Spasmolyt			S	Unknown	1 Df, Qd		Not Reported
	Spasmolyt			S	Unknown	15 Mg, Qd		Not Reported
	Tocilizumab			S	Subcutaneous	162 Mg, Qw		Not Reported
	Tocilizumab			S	Subcutaneous	162 Mg, Qw		Not Reported
	Ambrisentan			S	Unknown	Unk		Not Reported
	Quensyl			S	Unknown	40 Mg, Qd (1 Df, Bid (1 - 0 - 1))		Not Reported
	Quensyl			S	Unknown	40 Mg, Qd (20 Mg Bid)		Not Reported
	Volibris			S	Unknown	Unk		Not Reported
	Volibris			S				Not Reported
	Eliquis			S	Unknown	2 Df, Qd		Not Reported
	Eliquis			S	Unknown	2 Df, Qd		Not Reported
	Lyrica			C	Unknown	300 Mg, Qd (100 Mg, Tid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17262892	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00			Female	CAN

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

Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Mobicox		S	Oral		Boehringer Ingelheim
	Actemra		S	Subcutaneous		Not Reported
	Arava		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
	Methotrexate		S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		S	Unknown		Not Reported
	Sulfasalazine		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17263189	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516580		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide [Indapamide]			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported

Naprosyn [Naproxen]	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17263462	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516617			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17263578	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516715		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17263625	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518053		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	600mg		Not Reported
	Codeine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Tylenol	C		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Methylprednisolone	C		Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Acetaminophen	C		Not Reported
	Acetaminophen;Caffeine	C		Not Reported
	Caffeine;Codeine;Paracetamol	C		Not Reported
	Acetaminophen;Codeine Phosphate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17263658	EXPEDITED (15-DAY)		OT	CA-SA-2020SA006286			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Pain	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Pregabalin			S	Oral	150 Mg, Bid		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Tylenol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17263674	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2516064			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled		Not Reported

Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Enbrel	S	Syringe Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17264176	EXPEDITED (15-DAY)		OT	CA-SA-2020SA006216			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Leflunomide			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Otezla			S				Not Reported
	Simponi			S				Not Reported
	Stelara			S				Not Reported
	Xeljanz			S				Not Reported
	Cosentyx			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17264709	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020010755			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer

Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unk		Not Reported
Simponi	S	Subcutaneous			Not Reported
Salazopyrin	C	Unknown			Not Reported
Sulfasalazine	C	Unknown	1 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17265129	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-20K-028-3223218-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Blindness Unilateral; Condition Aggravated; Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension; Inflammation; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Pain; Pancreatitis; Peripheral Swelling; Pneumonia; Psoriatic Arthropathy; Scar	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17265159	EXPEDITED (15-DAY)		OT	CA-ROCHE-2515435		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Pharyngeal Oedema; Poor	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17265181	EXPEDITED (15-DAY)		OT	CA-ROCHE-2515486		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown	Therapy Duration: 9.0 Months		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4.0 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 4.0 Years		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported

Methotrexate	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Years		Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Arava	S	Oral			Not Reported
Piroxicam	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17265190	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-00119		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acquired Pigmented Retinopathy; Ocular Toxicity	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	12689305	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1444		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Contraindicated Product Administered; Drug	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Celecoxib	S	Unknown	Not Reported
	Apo Celecoxib	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	12911732	EXPEDITED (15-DAY)		HO, OT	BR-GLAXOSMITHKLINE-BR2016GSK144075		45 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aggression; Arthropathy; Asthenia; Circumstance Or Information Capable Of Leading To Medication	Benlysta			S		Unk Unk, Cyc		Glaxosmithkline
	Benlysta			S		Unk, Cyc		Glaxosmithkline
	Benlysta			S		Unk, Cyc		Glaxosmithkline

Error; Inappropriate Schedule Of Product Administration; Malaise; Metabolic Surgery; Nausea; Overdose; Product Dose Omission; Pyelonephritis; Sinusitis; Somnolence; Tachycardia; Tendon Rupture; Weight Decreased; Weight Loss Poor	Benlysta	S	Unk	Glaxosmithkline
	Benlysta	S	Unk	Glaxosmithkline
	Benlysta	S	820 Mg, Unk	Glaxosmithkline
	Benlysta	S	930 Mg, Unk	Glaxosmithkline
	Benlysta	S	Unk	Glaxosmithkline
	Benlysta	S	Unk	Glaxosmithkline
	Benlysta	S	Unk	Glaxosmithkline
	Benlysta	S	Unk	Glaxosmithkline
	Benlysta	S	Unk	Glaxosmithkline
	Prednisone	S	Unk	Not Reported
	Reuquinol	S	Unk	Not Reported
	Azathioprine	C	Unk	Glaxosmithkline
	Ketoprofen Lysine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	15630696	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105381		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection; Treatment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Nystatin			S	Unknown			Not Reported

Failure	Nystatin		S	Unknown		Not Reported
	Adalimumab		S	Subcutaneous	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Indometacin		C	Unknown		Not Reported
	Tramadol		C	Unknown		Not Reported
	Prednisone		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	16387992	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029849		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Treatment Failure	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Methotrexate			S	Subcutaneous	20 Milligram, Every 1 Week		Not Reported
	Methotrexate			S	Subcutaneous	20.0 Milligram, 4 Every 1 Week		Not Reported
	Plaquenil			S	Oral	200.0 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Two Times A Day		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Voltaren			S	Oral	75 Milligram, Two Times A Day		Not Reported
	Diclofenac			S	Oral	75.0 Milligram, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17050039	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1137045		43 YR	Female	CAN

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

Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Musculoskeletal Stiffness; Off Label Use; Pain; Therapeutic Product Effect Decreased; Treatment Failure	Prednisone		S	Unknown		Actavis
	Methotrexate		S	Unknown	2.8571 Milligram Daily;	Barr
	Minocycline Hydrochloride		S	Unknown		Actavis
	Enbrel		S	Subcutaneous		Not Reported
	Gold		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil		S	Unknown		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17227609	EXPEDITED (15-DAY)		HO	CA-ROCHE-2415329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported

	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17258422	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-ASTRAZENECA-2020SE03451			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy; No Adverse Event; Oligohydramnios; Premature Baby	Metoprolol Tartrate			S	Transplacental	Unk		Not Reported
	Omeprazole			S	Transplacental	Unk		Not Reported
	Vitamin K Nos			S	Transplacental	Unk		Not Reported
	Bisulepin			S	Transplacental	Unk		Not Reported
	Etamsylate			S	Transplacental	Unk		Not Reported
	Privigen			S	Transplacental	Unk		Not Reported
	Privigen			S	Transplacental	Unk		Not Reported
	Flebogamma Dif [Immunoglobulin Human Normal]			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Potassium Chloride			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Vitamin B Complex			S	Unknown	Unk		Not Reported
	Albumin			S	Transplacental	Unk		Not Reported
	Paracetamol			S	Transplacental	Unk		Not Reported
	Calcium Carbonate			S	Transplacental	Unk		Not Reported
	Ornidazole			S	Transplacental	Unk		Not Reported
	Cefixime			S	Transplacental	Unk		Not Reported
	Fluconazole			S	Transplacental	Unk		Not Reported
	Magnesium Lactate			S	Transplacental	Unk		Not Reported
	Methylprednisolone			S	Transplacental	Unk		Not Reported
	Methylprednisolone			S	Transplacental	Unk		Not Reported

Bisoprolol Fumarate	S	Transplacental	Unk		Not Reported
Folic Acid	S	Transplacental	Unk		Not Reported
Cefotaxime	S	Transplacental	Unk		Not Reported
Cefotaxime	S	Transplacental	Unk		Not Reported
Hydroxychloroquine	S	Transplacental	Unk		Not Reported
Hydrocortisone	S	Transplacental	Unk		Not Reported
Vulmizolin	S	Transplacental	Unk		Not Reported
Penicillin G [Benzylpenicillin Sodium]	S	Transplacental	Unk		Not Reported
Aminomethylbenzoic Acid	S	Transplacental	Unk		Not Reported
Vitamin D [Colecalciferol]	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17265226	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516327		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methylprednisolone			S	Unknown			Not Reported

Orencia	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Naproxen	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17265311	EXPEDITED (15-DAY)		OT	CA-ROCHE-2262233		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Subcutaneous	Therapy Duration: 5.0 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 11 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 5.0 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration: 5.0 Years		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 5.0 Years		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17265328	EXPEDITED (15-DAY)		OT	CA-ROCHE-2515630			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Tiaprofenic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17265486	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202001000189			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Erythema; Hepatitis Acute; Hypersensitivity; Oedema; Skin Plaque; Urticaria	Hydroxychloroquine			S	Unknown	200 Mg		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Humira			S	Unknown	Unk		Not Reported

	Orencia			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17265537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516963			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17265634	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0208		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported

Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Infliximab	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil S	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Cortisone	C	Unknown	Not Reported
	Dexamethasone	C	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported
	Reactine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17265651	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516779			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17265740	EXPEDITED (15-DAY)		HO	CA-ROCHE-2518159		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Sputum Discoloured; Thrombosis	Methotrexate		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Warfarin		S	Unknown	Not Reported
	Amitriptyline		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266000	EXPEDITED (15-DAY)		DS	CA-ROCHE-2516492		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	365		Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported

Enbrel	S	Subcutaneous		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Fosamax	S	Oral		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)	365	Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Prednisone	S	Oral	365.0	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	365.0	Not Reported
Sulfasalazine	S	Oral	365.0	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Tofacitinib Citrate	S	Unknown		Not Reported
Topicort [Desoximetasone]	S	Cutaneous		Not Reported
Salazopyrin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266020	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202001000206			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Pneumonia; Pulmonary Mass; Tinnitus	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Nexium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266022	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2020AP005966		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Cyclobenzaprine			S	Oral	Unk, Unknown		Apotex
	Esomeprazole			S	Oral	Unk, Unknown		Not Reported
	Hydroxychloroquine			S	Oral	Unk, Unknown		Not Reported
	Clindamycin			S	Oral	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266167	NON-EXPEDITED			US-CELGENEUS-USA-20200103523		64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dyspepsia; Eczema; Nodule; Psoriatic Arthropathy; Weight Decreased	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S	Oral	60 Milligram		Celgene
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266374	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202001000210			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Methotrexate			S	Oral	25 Mg, Weekly (12.5 Mg, Two Doses In One Day, Weekly)		Not Reported
	Methotrexate			S	Unknown	Increased To 20 Mg		Not Reported
	Prevnar 13			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266811	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020010649			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Seizure; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		10 Mg, 1x/Day		Not Reported
	Arava			S		20 Mg, 1x/Day		Not Reported
	Cimzia			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266914	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020012778			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Drug	Methotrexate Sodium			S	Unknown			Pfizer

Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis	Sulfasalazine		S	Unknown	1 G, 2x/Day	Pfizer
	Humira		S	Subcutaneous	40 Mg, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine		S	Unknown	400 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266960	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020013075			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Liver Function Test Increased; Sepsis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Unknown
	Pamidronate Disodium			S	Unknown	Unk		Unknown
	Azathioprine			S	Unknown	150 Mg, 1x/Day		Not Reported
	Bromocriptine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Dilaudid			C		Unk		Not Reported
	Mercaptopurine			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Tenoxicam			C		Unk		Not Reported
	Ustekinumab			C	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266977	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020012790		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Methotrexate Sodium			S	Unknown	Unk, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S	Unknown	200 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17267074	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020015344		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma	Tahor			S	Oral	1 Df, 1x/Day		Pfizer
	Plaquenil S			S	Oral	400 Mg, Unk		Not Reported
	Coumadine			S	Oral	Unk		Not Reported
	Anastrozole			S	Oral	1 Mg, 1x/Day		Not Reported
	Kardegic			S	Oral	1 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17267089	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517549		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Calcium Carbonate	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Imitrex [Sumatriptan]	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Sumatriptan	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17267572	EXPEDITED (15-DAY)		OT	NVSC2020US006167		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Dyspnoea Exertional; Orthopnoea	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17268186	EXPEDITED (15-DAY)		OT	CA-ROCHE-2515549		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

Cimzia	S	Subcutaneous		Not Reported
Folic Acid	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17269607	EXPEDITED (15-DAY)		OT	CA-SA-2020SA006940			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Diphenhydramine Hydrochloride			S	Unknown	Unk Unk, Unk		Sanofi
	Celecoxib			S	Oral	Unk Unk, Unk		Not Reported
	Demerol			S	Unknown	Unk Unk, Unk		Sanofi
	Levofloxacin			S	Unknown	Unk Unk, Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S				Sanofi
	Azithromycin			S	Unknown	250 Mg		Not Reported
	Cyclophosphamide			S	Unknown	Unk Unk, Unk		Not Reported
	Cimzia			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Unknown	Unk Unk, Unk		Not Reported
	Imuran [Azathioprine]			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Simponi			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

	Ezetrol			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17269873	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020013014			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Urine Abnormal; Cutaneous Sarcoidosis; Drug Ineffective; End Stage Renal Disease; Ocular Sarcoidosis; Proteinuria; Pulmonary Sarcoidosis	Infliximab			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S		Unk		Unknown
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	15887212	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0806		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Intolerance; Synovitis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown	Received 3 Doses		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	16479864	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2019-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Prescribed Underdose; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Triamcinolone Aq			S	Intra-articular	Spray, Metered Dose		Not Reported
	Apo-Triamcinolone Aq			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immune Globulin Intravenous (Human)			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Kineret			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate Sodium			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S				Not Reported

Triamcinolone	S	Intra-articular	Unknown		Not Reported
Triamcinolone	S	Unknown	Unknown		Not Reported
Sulfasalazine	S	Oral			Not Reported
Folic Acid (Natural Factors)	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	16940157	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201910001250			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Contraindicated Product Administered; Drug Intolerance; Maculopathy; Thrombocytopenia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Certolizumab Pegol			C	Subcutaneous	200 Mg, Every 2 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17047581	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019491577		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Intestinal Perforation	Methotrexate Sodium			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17134934	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019530204			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Infliximab			S	Intravenous (not otherwise specified)	200 Mg, 1 Every 8 Week (S)		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, 1 Every 15 Day(S)		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, 1 Every 15 Day(S)		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, 1 Every 2 Week(S)		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	100 Mg, 1 Every 1 Day(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, 1 Every 2 Day(S)		Not Reported
	Glyburide			C		750 Mg, 1x/Day		Not Reported
	Infliximab			C		Unk		Not Reported
	Lipitor			C		10 Mg, 1x/Day		Not Reported
	Metformin			C	Oral	Unk, 2x/Day		Not Reported
	Mycophenolate Mofetil			C	Oral	750 Mg, 2x/Day		Not Reported
	Prednisone			C		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17186676	EXPEDITED (15-DAY)		OT	NVSC2019CA075072			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Arava	S	Unknown	Unk		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Fosamax	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk (Solution)		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk (Solution)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17211778	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201912003172			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Gastrointestinal Disorder; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	10 Mg		Not Reported
	Methotrexate			S	Unknown	15-25 Mg Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17270824	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-00077		24 YR	Female	USA

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

Dry Skin; Oral Discomfort; Pruritus; Type Iv Hypersensitivity Reaction; Urticaria	Hydroxychloroquine Sulfate	S	Unknown	0.2 Milligram In A Solution Of 0.4 Ml	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	0.4 Milligram In A Solution Of 0.8 Ml, (0.5 Hours)	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	0.8 Milligram In A Solution Of 1.6 Ml (1 Hours)	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	1.6 Milligram In A Solution Of 3.1 Ml (1.5 Hours)	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	3.1 Milligram In A Solution Of 6.3 Ml (2.0 Hours)	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	6.3 Milligram In A Solution Of 12.5 Ml (2.5 Hours)	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	12.5 Milligram In A Solution Of 25.0 Ml (3.0 Hours)	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	25.0 Milligram In A Solution Of 50 Ml (3.5 Hours)	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	50 Milligram In A Solution Of 100 Ml (4.0 Hours)	Lupin
	Hydroxychloroquine Sulfate Tablets	S	Unknown	100 Milligram, Unk (4.5 Hours)	Lupin
	Hydroxychloroquine Sulfate Tablets	S	Unknown	100 Milligram, Unk (5 Hours)	Lupin
	Hydroxychloroquine Sulfate Tablets	S	Unknown	100 Milligram, Qd (Maintained As A Daily Medication)	Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17270841	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000193			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Cardiotoxicity; Dyspnoea Exertional;	Hydroxychloroquine			S	Unknown	Unk		Concordia

Heart Rate Increased; Orthopnoea; Oxygen Saturation Decreased; Rales; Respiratory Rate Increased; Restrictive Cardiomyopathy; Systolic Dysfunction; Ventricular Dysfunction

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17270846	EXPEDITED (15-DAY)		CA	DE-ADVANZ PHARMA-202001000236			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure Timing Unspecified; Trisomy 18	Hydroxychloroquine			S	Transplacental	Unk (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17270854	EXPEDITED (15-DAY)		OT	JP-LUPIN PHARMACEUTICALS INC.-2020-00131		68 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance	Methylprednisolone			S	Intravenous (not otherwise specified)	1 Gram, Qd For 3 Day		Lupin
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Prednisolone			S	Oral	40 Milligram, Qd		Not Reported
	Prednisolone			S	Oral	8 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17271142	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0313			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Salazopyrin	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17271143	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0270			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Intolerance; Interstitial Lung Disease; Pulmonary Mass; Sinusitis; Synovitis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17271230	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201705-002832			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Pneumonitis; Pneumothorax	Hydroxychloroquine			S	Oral	Unk		Concordia
	Arava			S	Oral	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk, Injection For Solution		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	Unk,Capsule, Hard		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Naproxen			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17271386	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517547		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17271513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518112		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Product Use In Unapproved Indication; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17271613	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518757		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C				Not Reported
	Enablex [Darifenacin]			C	Unknown			Not Reported
	Lasix [Furosemide]			C	Unknown			Not Reported
	Loperamide			C				Not Reported
	Norflex [Orphenadrine Citrate]			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported
	Pantoprazole Sodium Anhydrous			C				Not Reported
	Synthroid			C	Unknown			Not Reported
	Vagifem			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17271879	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516082		76 YR	Female	CAN

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

Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Anakinra	C	Unknown	Not Reported
	Ativan	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Darifenacin Hydrobromide	C	Unknown	Not Reported
	Dexamethasone	C	Intramuscular	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Kadian	C	Unknown	Not Reported

Loperamide	C	Unknown	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Triamcinolone Acetonide	C	Intra-articular	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17272044	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020012847			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Joint Stiffness; Nausea; Pain; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate Sodium			S	Oral	7.5 Mg, Unk		Pfizer
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5.0 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17272058	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020010657		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased;	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Tofacitinib Citrate			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported

Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Adalimumab	S	Unknown	40 Mg, 2x/Day	Not Reported
	Ciclosporin	S		Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	125 Mg, Weekly	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Gabapentin	C	Oral	400 Mg, 3x/Day	Not Reported
	Tylenol Arthritis	C		650 Mg, 4x/Day	Not Reported
	Xeljanz	C	Oral	5 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17272121	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020016060			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Frequent Bowel Movements; Rash; Retinal Toxicity; Stomatitis	Methotrexate Sodium			S	Unknown	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17272585	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-BAUSCH-BL-2020-000639			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy; No Adverse Event; Oligohydramnios; Premature Baby	Hydrocortisone			S	Transplacental			Not Reported
	Dexamethasone			S	Transplacental			Bausch And Lomb
	Dexamethasone			S	Transplacental			Bausch And Lomb
	Bisoprolol Fumarate			S	Transplacental			Not Reported
	Vitamin K Nos			S	Transplacental			Not Reported

Bisulepin	S	Transplacental	Not Reported
Nadroparine	S	Transplacental	Not Reported
Etamsylate	S	Transplacental	Not Reported
Privigen	S	Transplacental	Not Reported
Privigen	S	Transplacental	Not Reported
Flebogamma Dif [Immunoglobulin Human Normal]	S	Transplacental	Not Reported
Metoprolol Tartrate	S	Transplacental	Not Reported
Potassium Chloride	S	Transplacental	Not Reported
Prednisone	S	Transplacental	Not Reported
Prednisone	S	Transplacental	Not Reported
Vitamin B Complex	S	Unknown	Not Reported
Albumin	S	Transplacental	Not Reported
Paracetamol	S	Transplacental	Not Reported
Calcium Carbonate	S	Transplacental	Not Reported
Ornidazole	S	Transplacental	Not Reported
Cefixime	S	Transplacental	Not Reported
Fluconazole	S	Transplacental	Not Reported
Magnesium Lactate	S	Transplacental	Not Reported
Methylprednisolone	S	Transplacental	Not Reported
Methylprednisolone	S	Transplacental	Not Reported
Folic Acid	S	Transplacental	Not Reported
Omeprazole	S	Unknown	Not Reported
Cefotaxime	S	Transplacental	Not Reported
Cefotaxime	S	Transplacental	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Vulmizolin	S	Transplacental	Not Reported
Penicillin G [Benzylpenicillin Sodium]	S	Transplacental	Not Reported
Aminomethylbenzoic Acid	S	Transplacental	Not Reported

	Vitamin D [Colecalciferol]	S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2020	17274758	EXPEDITED (15-DAY)		DE, OT	US-BEH-2020111543		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Product Use In Unapproved Indication; Stillbirth	Human Immunoglobulin (Inn)			S	Intravenous (not otherwise specified)			Csl Behring
	Methylprednisolone			S	Unknown			Not Reported
	Dexamethasone			S	Unknown			Not Reported
	Etoposide			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	8644662	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-16703324		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Faeces Discoloured; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Swelling;	Abatacept			S	Unknown	Inf:8,Last Infusion On 24-May-2012 Last Infusion On 15-Jan-2014. 3j75953-Exp Date:Jul-2016.		Bristol Myers Squibb
	Abatacept			S	Unknown			Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	1 Df, Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported

Knee Arthroplasty; Liver Function Test Abnormal; Malaise; Meniscus Injury; Neuropathy Peripheral; Off Label Use; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Paraplegia; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Disorder; Spinal Stenosis; Treatment Failure; Upper Respiratory Tract Infection	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Arava	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Mg, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2 G, A Day	Not Reported
	Tramadol Hydrochloride And Acetaminophen	S	Unknown		Not Reported
	Tramacet	S	Unknown	Unk	Not Reported
	Tramacet	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Prednisone	C	Unknown		Not Reported
	Oxycocet	C	Unknown		Not Reported
	Lyrica	C	Oral	150 Mg, Bid	Not Reported
	Amitriptyline	C	Unknown		Not Reported
	Nortriptyline	C	Unknown	2 Tab, Unk	Not Reported
	Nortriptyline	C	Unknown		Not Reported
	Depo-Medrol	C	Subcutaneous	Unk, Qmo	Not Reported
	Depo-Medrol	C	Intramuscular	Unk, Qmo	Not Reported
	Metformin	C	Unknown	500 Mg, Bid	Not Reported
	Metformin	C	Unknown	5 Milligram, Qd	Not Reported
	Lorazepam	C	Unknown	1 Milligram, Qd	Not Reported
	Vagifem	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	0.625 Milligram	Not Reported
	Vitamin D [Ergocalciferol]	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Tylenol Arthritis	C	Unknown		Not Reported
	Actonel	C	Unknown	35 Milligram, Qwk	Not Reported

Methylprednisolone Acetate	C	Unknown		Not Reported
Methylprednisolone Acetate	C	Subcutaneous	Unk, Qmo	Not Reported
Methylprednisolone Acetate	C	Subcutaneous	40 Milligram, Qmo	Not Reported
Methylprednisolone Acetate	C	Intramuscular	40 Milligram, Qmo	Not Reported
Ergocalciferol	C	Unknown		Not Reported
Nortriptylin	C	Unknown	20 Milligram, Qd	Not Reported
Nortriptylin	C	Unknown		Not Reported
Risedronate Sodium	C	Unknown	35 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	15663618	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2018-CA-980916		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Event; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Dyspepsia; Fatigue; Gastric Disorder; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Leflunomide			S	Unknown			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Myochrysine			S	Parenteral			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Myochrysine			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported
	Rituxan			S	Unknown			Not Reported

Sirukumab	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Stelara	S	Unknown		Not Reported
Stelara	S	Subcutaneous		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tofacitinib Citrate	S	Oral	10 Milligram Daily;	Not Reported
Ustekinumab	S	Unknown		Not Reported
Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apremilast	S	Unknown		Not Reported
Minocin	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Unknown		Not Reported
Cosentyx	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported
Orencia	C	Unknown		Not Reported
Orencia	C			Not Reported
Simponi	C	Subcutaneous		Not Reported
Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	16226755	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1145		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Compression	Sulfasalazine	S	Unknown	Die		Not Reported
	Hydroxychloroquine	S	Unknown	Die		Not Reported
	Hydroxychloroquine	S	Unknown	Die		Not Reported
	Actemra	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	16821832	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019397200		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobile; Malaise	Celebrex			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, 1x/Day		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Naprosyn [Naproxen Sodium]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17274874	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-002161			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17274895	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201802-000579			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Paraesthesia; Rash; Rash; Rheumatoid Arthritis; Swelling Of Eyelid	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17275168	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-233249		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma	Anastrozole			S	Oral	1 Milligram, Daily		Sun
	Tahor 10 Mg, Comprime Pellicule			S	Oral	1 Dosage Form, Daily		Not Reported
	Plaquenil			S	Oral	400 Milligrams, Unk		Not Reported
	Coumadine			S	Oral	Unk		Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose			S	Oral	1 Dosage Form, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17275252	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518338			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17275270	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518354			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17275291	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0354			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pneumonia; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17275294	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0360			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Seizure; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17275296	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0378			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17275422	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000260			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Dermatitis Allergic; Drug Ineffective; Lower Limb Fracture; Pain; Skin Lesion; Spinal Fracture; Weight Increased; Wrist Fracture	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17277879	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020016043			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pancytopenia; Rash	Methotrexate Sodium			S		Unk		Unknown
	Sulfasalazine			S	Unknown	1 G, 2x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Asaphen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17277884	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020016034		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate Sodium			S				Unknown
	Sulfasalazine			S				Pfizer
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C		7.5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17277886	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020015828			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin	Methotrexate Sodium			S		Unk		Unknown
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S		Unk		Not Reported

Irritation; Weight Increased	Plaquenil S	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported
	Ibuprofen	C	600 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17278312	EXPEDITED (15-DAY)		OT	NVSC2019CA086423		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Folic Acid			S	Unknown	Unk		Not Reported
	Folic Acid			S	Oral	5 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	1 Df, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Cetrizine			S	Unknown	10 Mg		Not Reported
	Cetrizine			S	Unknown	25 Mg		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Hydrocortisone Acetate			S	Subcutaneous	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S				Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Mg	Not Reported
Hydrocortisone	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil	S	Oral	400 Mg, Qd	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Sulfasalazine	S	Oral	1 G, Qd	Not Reported
Sulfasalazine	S	Subcutaneous	1 G, Qd	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Topicort	S	Subcutaneous	Unk	Not Reported
Topicort	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Qd	Not Reported
Atasol	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17278675	EXPEDITED (15-DAY)		OT	NVSC2019CA062116			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	Unk		Novartis
	Methotrexate Sodium			S	Unknown	25 Mg, Every 6-8 Weeks		Novartis
	Cortisone			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17278853	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-00516			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported

Plaquenil	S	Unknown	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported
Xeljanz	S	Unknown	Unknown		Not Reported
Naproxen	C	Unknown	Unknown		Not Reported
Prednisone	C	Unknown	Unknown		Not Reported
Rituxan	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17279247	NON-EXPEDITED			NVSC2020US008095		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication	Prednisone			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17279295	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518789			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported

	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17279325	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020018918			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Enbrel			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17279336	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2517211		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported

Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		Not Reported
	Nasonex	C		Not Reported
	Esomeprazole	C		Not Reported
	Nortriptyline	C		Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]	C		Not Reported
	Oxycodone Terephthalate	C		Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]	C		Not Reported
	Prednisone	C		Not Reported
	Trazodone	C		Not Reported
	Tylenol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17279781	NON-EXPEDITED			NVSC2020US008032		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropsychiatric Symptoms; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jan-2020	17279805	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA017708			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper;	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported

Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Etanercept	S	Subcutaneous	50 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, 2x/Day	Not Reported
	Xeljanz	S	Oral	5 Mg, Daily	Not Reported
	Xeljanz	S	Oral	5 Mg, 2x/Day	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	9 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Weeks	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Daily	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Daily	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil S	S	Unknown	200 Mg, Daily	Not Reported
	Prednisone	S	Unknown	9 Mg, Daily	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Acetaminophen	C			Not Reported
	Cortisone [Hydrocortisone]	C			Not Reported
	Dexamethasone	C			Not Reported
	Gabapentin	C			Not Reported
	Reactine [Cetirizine Hydrochloride]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	10977909	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015025803		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Drug Intolerance; Synovitis	Enbrel			S	Subcutaneous	50 Mg, Weekly		Amgen
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Daily		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Monthly		Not Reported
	Simponi			S	Subcutaneous	50 Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Remicade			S	Unknown	3 Milligram/Kilogram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	300 Milligram, Daily		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	200 Mg, (Every 4 Weeks)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	12990786	EXPEDITED (15-DAY)			US-VALIDUS PHARMACEUTICALS LLC-US-2016VAL002141			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Furosemide			S	Intravenous drip	80 Mg, Qd		Validus
	Furosemide			S				Validus
	Prednisone			S	Unknown	40 Mg, Qd		Not Reported
	Prednisone			S	Unknown	100 Mg, Qd		Not Reported
	Prednisone			S				Not Reported
	Methylprednisolone			S	Unknown	250 Mg, Q6h		Not Reported
	Methylprednisolone			S				Not Reported

Hydroxychloroquine	S	Unknown	200 Mg, Bid		Not Reported
Isosorbide Mononitrate	S	Unknown	Unk		Not Reported
Carvedilol	S	Oral	12.5 Mg, Tid		Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	500 Mg, Unk		Not Reported
Cyclophosphamide	S				Not Reported
Azathioprine	S	Unknown	50 Mg, Tid		Not Reported
Hydralazine	S	Unknown	25 Mg, Tid		Not Reported
Nitroglycerine	S	Intravenous (not otherwise specified)	60 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	13519807	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038321		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Erythema; Hand Deformity; Hepatic Fibrosis; Joint Swelling; Liver Function Test Increased; Musculoskeletal Pain; Nausea; Nodule; Osteoarthritis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Factor Positive	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	14295590	NON-EXPEDITED		OT	US-PFIZER INC-2017538711		70 YR	Female	USA

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

Drug Hypersensitivity; Rash	Methotrexate Sodium	S	Oral	Unk		Pfizer
	Hydroxychloroquine	S	Oral	Unk		Not Reported
	Plaquenil	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	14815472	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110703		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Bone Cyst; Bone Erosion; C-Reactive Protein Abnormal; Diabetes Mellitus; Drug Ineffective; Hepatic Steatosis; Hypertension; Joint Ankylosis; Joint Swelling; Liver Disorder; Musculoskeletal Stiffness; Osteolysis; Pain; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Response Decreased; Upper Respiratory Tract Infection	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Therapy Duration: 12.0 Month(S)		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Remicade	S	Unknown	Not Reported
	Infliximab	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	16298203	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121443			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Spinal Compression Fracture	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Oral	Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Actemra			S	Unknown	Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg 40mg/0.8ml		Not Reported
	Xeljanz			S	Unknown	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	16300431	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121442		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Arava			S	Oral	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Sanofi
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	100 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	16965363	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019457898		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobile; Malaise	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Arava			S		20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		400 Mg, 1x/Day		Not Reported
	Prednisone			S		Unk		Not Reported
	Naprosyn [Naproxen]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17149061	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20191206550		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use;	Motrin			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Motrin			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Aspirin /00002701/			S	Unknown			Not Reported
	Aspirin /00002701/			S	Unknown			Not Reported
	Aspirin /00002701/			S	Unknown			Not Reported
	Aspirin /00002701/			S	Unknown			Not Reported

Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Diclofenac	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac Potassium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported

Plaquenil /00072602/	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Vitamin C /00008001/	S	Unknown	Not Reported
Apo Hydroxychloroquine	S	Unknown	Not Reported
Apo-Diclofenac	S	Unknown	Not Reported
Voltaren /00372301/	S	Unknown	Not Reported
Sulfametoxazol/Trimetoprim	S	Unknown	Not Reported
Tramadol Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17223339	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-109009		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Drug Interaction; Off Label Use; Product Use In Unapproved Indication	Amlodipine Tablets			S	Unknown	Unk		Aurobindo
	Ramipril			S	Oral	Unk		Aurobindo
	Esomeprazole			S	Unknown	Unk		Not Reported
	Boswellia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Thyroxine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17280132	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-087058		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition	Pantoprazole			S	Unknown	40 Milligram, Once A Day		Aurobindo
	Naproxen			S	Oral	100 Milligram, Once A Day		Not Reported
	Naproxen			S	Oral	500 Milligram, Two Times		Not Reported

Aggravated; Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis				A Day	
	Naproxen	S	Oral	1000 Milligram, Once A Day	Not Reported
	Folic Acid	S	Unknown	5 Milligram, Twice In A Week	Not Reported
	Folic Acid	S	Unknown	400 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram, Two Times A Day	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Two Times A Day	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	40 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Two Times A Day	Not Reported
	Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Atenolol	S	Unknown	25 Milligram, Once A Day	Not Reported
	Sulfasalazin	S	Oral	500 Milligram, Two Times A Day	Not Reported
	Sulfasalazin	S	Oral	1000 Milligram, Two Times A Day	Not Reported
	Co Atenolol	S	Unknown	25 Milligram, Once A Day	Not Reported
	Co Atenolol	S	Unknown	20 Milligram, Once A Day	Not Reported
	Methotrexate Sodium	S	Unknown	20 Milligram, Every Week	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Every Week	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, 1 Every 2 Weeks	Not Reported
	Palafer Cf	S	Unknown	Unk Unk, Once A Day	Not Reported
	Pantoloc	S	Unknown	40 Milligram, Once A Day	Not Reported
	Arava	S	Unknown	20 Milligram, Once A Day	Not Reported
	Naprosyn	S	Oral	500 Milligram, Two Times	Not Reported

			A Day	
Naprosyn	S	Oral	1000 Milligram, Once A Day	Not Reported
Naprosyn	S	Oral	100 Milligram, Once A Day	Not Reported
Plaquenil	S	Unknown	200 Milligram, Two Times A Day	Not Reported
Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
Plaquenil	S	Unknown	40 Milligram, Once A Day	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk Unk, Once A Day	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Ascorbic Acid	S	Unknown	Unk	Not Reported
Ascorbic Acid	S	Unknown	Unk Unk, Once A Day	Not Reported
Ferrous Fumarate	S	Unknown	Unk	Not Reported
Ferrous Fumarate;Folic Acid	S	Unknown	Unk, Once A Day	Not Reported
Humira	S	Subcutaneous		Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Naproxen Sodium	S	Oral	100 Milligram, Two Times A Day	Not Reported
Naproxen Sodium	S	Unknown	500 Milligram, Two Times A Day	Not Reported
Naproxen Sodium	S	Oral	500 Milligram, Two Times A Day	Not Reported
Naproxen Sodium	S	Unknown	1000 Milligram, Once A Day	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram, 2 In Week	Not Reported
Prednisone	C	Unknown	5 Milligram, Once A Day	Not Reported
Celebrex	C	Oral	200 Milligram, Once A Day	Not Reported

	Celecoxib		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17280820	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0388		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17280830	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0413		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

	Gabapentin		C	Unknown	Not Reported
	Tylenol Arthritis		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17281759	EXPEDITED (15-DAY)		HO	CA-ROCHE-2520587		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ilaris			C	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17281792	EXPEDITED (15-DAY)		OT	CA-ROCHE-2520386		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoporotic Fracture; Spinal Compression	Actemra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported

Fracture	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Subcutaneous	Solution		Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Tylenol Arthritis Pain	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17281795	EXPEDITED (15-DAY)		LT	CA-ROCHE-2521035		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Dyspnoea; Odynophagia; Rheumatoid Arthritis; Stridor	Rituxan			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17281970	EXPEDITED (15-DAY)		OT	CA-ROCHE-2521190			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17282315	EXPEDITED (15-DAY)		OT	CA-ROCHE-2520406		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Ativan			C				Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Darifenacin Hydrobromide			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

	Dilaudid	C	Unknown	Not Reported
	Furosemide	C		Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Kadian	C		Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Unknown	Not Reported
	Lasix [Furosemide]	C	Unknown	Not Reported
	Morphine Sulfate	C	Unknown	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
	Omnaris	C	Unknown	Not Reported
	Oxyneo	C	Unknown	Not Reported
	Pantoloc [Pantoprazole]	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Restasis	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Trimethoprim	C	Unknown	Not Reported
	Urispas	C	Unknown	Not Reported
	Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17283057	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020020262			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported

	Plaquenil		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Stelara		S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17283096	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020020653		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17283466	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-00751			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported

Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Anakinra		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Gamastan		S	Intravenous (not otherwise specified)	Liquid Intramuscular	Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Naproxen Sodium		S	Unknown	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		S	Oral		Not Reported
	Prednisone		S	Oral		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Tocilizumab		S	Intravenous (not otherwise specified)		Not Reported
	Triamcinolone		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2020	14066264	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2017151683		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Reaction; Injection Site Urticaria; Nausea; Rash; Urticaria	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Oral	25 Milligram, Qd	Not Reported
	Simponi	C		Unk	Not Reported
	Atenolol	C	Oral	50 Milligram, Qd	Not Reported
	Inflectra	C	Intravenous (not otherwise specified)	300 Milligram,(Q0, 2,6, Week Then Every 8 Weeks	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2020	17285802	EXPEDITED (15-DAY)		OT	CA-ROCHE-2523752		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2020	17285810	EXPEDITED (15-DAY)		OT	CA-ROCHE-2523787		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Asa	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Lantus	C	Subcutaneous	Not Reported
	Lozide [Indapamide]	C	Unknown	Not Reported
	Naprosyn [Naproxen]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2020	17285884	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-00693			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence	Infliximab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen Sodium			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

In Daily Activities; Obesity;
Off Label Use;
Polyarthritis; Psoriasis;
Red Blood Cell
Sedimentation Rate
Increased; Septic Shock;
Synovitis; Underdose;
Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2020	17286046	EXPEDITED (15-DAY)		OT	CA-ROCHE-2521067		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Ophthalmic			Not Reported
	Zingiber Officinale			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2020	17286091	EXPEDITED (15-DAY)		OT	CA-ROCHE-2521085		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rosuvastatin			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2020	17256046	EXPEDITED (15-DAY)		OT	US-ABBVIE-20K-163-3220051-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Dermatitis Allergic; Drug Ineffective; Lower Limb Fracture; Pain; Skin Lesion; Spinal Fracture; Weight Increased; Wrist Fracture	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2020	17286444	EXPEDITED (15-DAY)		OT	CA-ROCHE-2521786			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Methotrexate		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Simponi		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2020	17286449	EXPEDITED (15-DAY)		OT	CA-ROCHE-2521764			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2020	17286597	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-00680			Unknown	CAN

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

Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Infliximab	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Adalimumab	S	Subcutaneous	Unknown	Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Triamcinolone	S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2020	17286603	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-00685			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported

Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Anakinra	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Naproxen Sodium	S	Unknown	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S	Oral			Not Reported
	Prednisone	S	Oral			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Triamcinolone	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jan-2020	17286607	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-00738			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Prednisone	S	Oral			Not Reported
	Prednisone	S				Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone	S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	12386748	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015095675		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Drug Intolerance; Synovitis	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Simponi			S	Subcutaneous	50 Mg, Monthly		Not Reported
	Simponi			S	Subcutaneous	50 Milligram		Not Reported
	Hydroxychloroquine			S		300 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		300 Mg, Daily		Not Reported
	Remicade			S		3 Mg/Kg, (Received 3 Doses)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	200 Mg, (Every 4 Weeks)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	12676434	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2016108897		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Contraindicated Product	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Administered; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celebrex	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	10 Milligram/Kilogram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Celecoxib	S	Unknown	Unk	Not Reported
	Celecoxib	S	Unknown	Unk	Not Reported
	Apo Celecoxib	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Hydromorphone	C		Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	2 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	14013022	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017408867		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonitis; Pulmonary Toxicity	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	14921463	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043742		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Off Label Use; Rash; Syncope; Urticaria	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qmo		Bristol Myers Squibb
	Actemra			S	Oral	4.0 Mg/Kg, Unk		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Qmo		Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported
	Prevacid			C	Unknown	30 Milligram, Bid		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	15560134	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018048332		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Dosage Form: Unspecified		Not Reported
	Cetirizine Hydrochloride			S		Dosage Form: Unspecified		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Actemra			S		Dosage Form: Unspecified		Not Reported
	Apo-Prednisone			S		5 Mg, Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Dosage Form: Unspecified		Not Reported
	Enbrel			S	Subcutaneous	Dosage Form: Unspecified		Not Reported
	Folic Acid			S		500 Mg, Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Fosamax			S		Intracorpus Route		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S		Dosage Form: Unspecified		Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Dosage Form: Unspecified		Not Reported
	Phthalylsulfathiazole			S		Dosage Form: Unspecified		Not Reported
	Plaquenil			S	Oral	400 Mg, Once Daily (Qd)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous		Not Reported
	Sulfasalazine			S	Oral	1 G Two Every 1 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cortisone Acetate			S				Not Reported
	Diclofenac Sodium			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	15560216	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181030392		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Fosamax			S	Intracavernous			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

Diclofenac Sodium	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	16298219	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121389			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Crohn'S Disease; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Urosepsis	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Q4w		Not Reported
	Certolizumab Pegol			S	Unknown	400 Mg, Qow		Not Reported
	Infliximab			S	Unknown	Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17090074	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP025456		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In	Metformin			S	Unknown	500 Mg, Bid		Apotex
	Desoximetasone			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Remicade		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Altace		C	Unknown	5 Mg, Qd	Not Reported
	Asa		C	Unknown	81 Mg, Qd	Not Reported
	Folic Acid		C	Unknown	Unk (6 Every 1 Week)	Not Reported
	Methotrexate		C	Oral	15 Mg, Qd	Not Reported
	Omega 3 /01333901/		C	Unknown	Unk	Not Reported
	Rosuvastatin Calcium		C	Unknown	20 Mg, Qd	Not Reported
	Vitamin D /00107901/		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17250549	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007215		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Off Label Use; Toxicity To Various Agents	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Sulfasalazine			C	Oral	Unk, 3 Every 1 Day		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17287208	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-00689			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Immunoglobulins Nos			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen Sodium			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone			S	Subcutaneous			Not Reported
	Triamcinolone Acetonide			S	Unknown	Unknown		Not Reported
	Triamcinolone Acetonide			S				Not Reported
	Triamcinolone Acetonide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17287257	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2520375		59 YR	Female	CAN

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

Back Disorder; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Hospitalisation; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Rheumatoid Arthritis; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Warfarin	S	Unknown	Not Reported
	Warfarin	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Amitriptyline	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17287417	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518697			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Personal Independence In Daily Activities; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17287533	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Joint Stiffness; Nausea; Pain; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17288010	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518271		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Rituxan	S	Intravenous drip	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Ciclosporin	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Neoral	S	Oral	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz Xr	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17288021	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-002228		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Loss Of Personal Independence In Daily	Pantoprazole			S	Unknown	Unk		Aurobindo
	Methotrexate			S	Unknown	20 Milligram, Every Week		Not Reported

Activities; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Treatment Failure	Plaquenil	S	Unknown	Unk	Not Reported
	Prinivil	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Two Times A Day	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Once A Day	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Voltaren Sr	S	Oral	Unk	Not Reported
	Voltaren Sr	S	Oral	75 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17288398	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2020SA013858		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Ill-Defined Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Oral	Qw (1 Every 1 Weeks)		Not Reported
	Methotrexate			S	Oral	4 Df, Qw		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Enbrel			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Remicade			S	Unknown	Unk Unk, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17288659	EXPEDITED (15-DAY)		HO, LT	NVSC2020GB011027		61 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Panic Attack; Psychotic Disorder; Self-Injurious Ideation; Suicidal Ideation	Methotrexate			S	Oral	25 Mg, Qw		Novartis
	Hydroxychloroquine Sulphate			S	Oral	400 Mg, Qd		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported

	Folic Acid			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17288976	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020023022			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Treatment Failure	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Enbrel			S	Unknown			Pfizer
	Tofacitinib Citrate			S	Unknown			Pfizer
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17288985	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020022973		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling;	Enbrel			S	Subcutaneous	1 Df, Weekly		Pfizer
	Lyrica			S	Oral	Unk		Pfizer
	Lyrica			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported

Therapeutic Product Effect Decreased	Glumetza	S	Unknown	500 Mg, 2x/Day	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Altace	C	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Asa	C	Unknown	Unk	Not Reported
	Codeine	C	Unknown	Unk	Not Reported
	D-Alpha Tocopherol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Prednisone	C	Oral	Unk	Not Reported
	Rosuvastatin Calcium	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17289048	EXPEDITED (15-DAY)		OT	CA-009507513-2001CAN006467		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Zenhale			S	Unknown	200 Microgram, Qd (1 Every 1 Days), Dosage Form: Metered Dose Aerosol		Merck
	Zenhale			S	Unknown	200 Milligram, Bid (2 Every		Merck

				1 Days)	
	Spiriva	S	Unknown	2.5 Milligram, Bid (2 Every 1 Days)	Not Reported
	Plaquenil	S	Oral	300 Milligram, Qd (1 Every 1 Days)	Not Reported
	Methotrexate	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
	Lipitor	S	Unknown	40 Milligram, Qd (1 Every 1 Days); Dosage Form: Not Specified	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qd (1 Every 1 Days)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17289327	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524706		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17289374	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524633		38 YR	Female	CAN

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

Bedridden; Crying; Drug Ineffective	Actemra		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Ergocalciferol		C	Unknown	Not Reported
	Leucovorin [Folinic Acid]		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17289411	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-00612			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Glyburide			C	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Metformin			C	Oral	Unknown		Not Reported
	Mycophenolate Mofetil			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17289758	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2020M1004729			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Spasmolyt			S	Unknown	30 Milligram, Qd(30 Mg, Qd)		Mylan
	Spasmolyt			S	Unknown	1 Dosage Form, Qd (1 Df, Qd)		Mylan
	Ambrisentan			S	Unknown	Unk		Not Reported
	Pregabalin			S	Unknown	3 Dosage Form, Qd(1 Df, 3x/Day (1 - 1- 1))		Not Reported
	Sildenafil			S	Unknown	60 Milligram, Qd		Not Reported
	Omeprazole			S	Oral	2 Dosage Form, Qd (1 Df, 2x/Day (1 - 0 - 1))		Not Reported
	Quensyl			S	Unknown	40 Milligram, Qd (1 Df, Bid (1 - 0 - 1))		Mylan
	Eliquis			S	Unknown	2 Dosage Form, Qd		Mylan
	Volibris			S		Unk		Mylan
	Volibris			S	Oral	Unk		Mylan
	Tocilizumab			S	Subcutaneous	162 Milligram, Qw		Mylan
	Tocilizumab			S	Subcutaneous	162 Milligram, Qw		Mylan
	Ramipril			S	Oral	2 Dosage Form, Qd (1 Df,2x/Day(1 - 0 - 1))		Mylan
	Eliquis			C	Unknown	5 Milligram, Qd(2.5 Mg Bid)		Mylan
	Ramipril			C	Unknown	5 Milligram, Qd		Mylan
	Spasmolyt			C	Unknown	15 Milligram, Qd		Mylan
	Quensyl			C	Unknown	40 Milligram, Qd(20 Mg Bid)		Mylan
	Lyrica			C	Unknown	300 Milligram, Qd(100 Mg, Tid)		Mylan

	Omeprazole		C	Unknown	40 Milligram, Qd (20 Mg, Bid)	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17289815	EXPEDITED (15-DAY)		OT	CA-PURDUE PHARMA-CAN-2020-0010523			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Morphine Sulfate			S	Unknown	Unk		Purdue
	Acetaminophen			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Indometacin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	12.5 Mg, Daily		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17289906	EXPEDITED (15-DAY)		OT	FR-BAUSCH-BL-2020-001503		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Exposure During Pregnancy	Pentoxifylline			S	Unknown			Not Reported
	Aspegic (Acetylsalicylic Acid)			S	Unknown			Not Reported
	Kardegic			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Lovenox			S	Unknown			Not Reported

	Gestarelle G	S	Unknown	Not Reported
	Doliprane	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Jan-2020	17290228	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1171101		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Restrictive Cardiomyopathy	Hydroxychloroquine			S	Unknown	Form Strength : Unknown		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	14921644	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044730		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Off Label Use; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Azathioprine			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Clavulin [Amoxicillin Sodium;Clavulanate Potassium]			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1500 Mg, Unk		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Ciprofloxacin Hydrochloride	S	Unknown		Not Reported
	Amoxicillin Sodium And Clavulanate Potassium	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown	200 Milligram, Bid	Not Reported
	Prednisone	C	Unknown	7.5 Milligram, Qd	Not Reported
	Tridural	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Cimetidine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	16676089	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2877461-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Ciclosporin			S	Oral			Not Reported

	Actemra	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Pregabalin	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Imuran	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	16831207	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3535		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobile; Malaise	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17168676	EXPEDITED (15-DAY)		OT	CA-ROCHE-1632257		72 YR	Male	CAN

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

Abdominal Distension; Abdominal Pain; Abdominal Pain Lower; Abscess Oral; Arthralgia; Asthenia; Barium Enema Abnormal; Blood Pressure Diastolic Abnormal; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Abnormal; Blood Pressure Systolic Increased; Body Temperature Decreased; Bursitis; Disease Susceptibility; Dry Throat; Dry Throat; Eye Disorder; Fatigue; Fatigue; Heart Rate Decreased; Hypoaesthesia; Insomnia; Musculoskeletal Stiffness; Nasopharyngitis; Oedema Peripheral; Palpitations; Polyp; Sinusitis; Tooth Disorder; Tooth Fracture	Rituxan	S	Intravenous (not otherwise specified)	Last Rituximab Dose: 08/Mar/2016	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Diphenhydramine Hydrochloride	C	Oral		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Celebrex	C			Not Reported
	Pantoloc [Pantoprazole]	C			Not Reported
	Ativan	C			Not Reported
	Norvasc	C			Not Reported
	Folic Acid	C			Not Reported
	Methotrexate	C			Not Reported
	Diltiazem	C			Not Reported
	Celebrex	C			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17221812	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-201912003220			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Hypersensitivity	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Zolpidem Tartrate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17257120	EXPEDITED (15-DAY)		DE, HO	CA-PFIZER INC-2020009000		67 YR	Male	CAN

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

Abdominal Pain; Bacteraemia; Body Temperature Increased; Central Nervous System Infection; Clostridium Difficile Infection; Confusional State; Decreased Appetite; Depressed Level Of Consciousness; Diarrhoea; Escherichia Infection; Headache; Nausea; Nervous System Disorder; Seizure; Somnolence; Stress Ulcer; Strongyloidiasis; Thrombosis; Upper Gastrointestinal Haemorrhage; Vomiting; Weight Decreased	Methotrexate Sodium	S	Unknown	Unknown
	Prednisone	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17265975	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202001000204			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis	Hydroxychloroquine			S	Unknown	200 Mg, Qod		Concordia
	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Rosuvastatin			C		Unk		Not Reported
	Bisoprolol Sandoz			C		Unk		Not Reported
	Jamp Calcium			C		Unk		Not Reported
	Teva Risedronate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17290394	EXPEDITED (15-DAY)		OT	CA-ROCHE-2525890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertensive Urgency; Presyncope	Rituximab			S	Unknown	Therapy Duration:- 7.0 Years		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration:- 7.0 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration:- 7.0 Years		Not Reported
	Methotrexate			S	Oral	Therapy Duration:- 7.0 Years		Not Reported
	Methotrexate			S	Unknown	Therapy Duration:- 7.0 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration:- 7.0 Years		Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration:- 7.0 Years		Not Reported
	Xeljanz			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17290456	EXPEDITED (15-DAY)		DE	CA-ROCHE-2528022		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Large B-Cell Lymphoma	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17290482	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0450			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17290592	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0462			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Otezla	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17290601	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0449		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17290629	EXPEDITED (15-DAY)		DE	CA-ROCHE-2528043		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Large B-Cell Lymphoma	Rituximab			S	Unknown			Not Reported

	Mycophenolate Mofetil	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Cyclophosphamide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17291357	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3240682-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis; Synovitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17291376	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0448		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Xeljanz	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Glumetza	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Arava	C	Unknown	Not Reported
	Altace	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Asa (Acetylsalicylic Acid)	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	D-Alpha Tocopherol	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17293254	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08483		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram,		Lupin

Unapproved Indication; Retinopathy	Qd, (Total Dose: 876 Grams)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17295082	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1005757		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antisynthetase Syndrome; Rebound Effect	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17295425	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020027208		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity	Methotrexate Sodium			S	Oral	30 Mg, Weekly(1 Every 1 Weeks)		Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, 1x/Day(1 Every 1 Days)		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Otezla			S	Unknown	30 Mg, 2x/Day(2 Every 1 Days)		Not Reported
	Prednisone			C	Unknown	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17295898	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020027399		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Hypogammaglobulinaemia; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17296317	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1004929		66 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Hepatocellular Injury; Weight Loss Poor	Doxycycline			S	Oral	200 Milligram, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	400 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17297064	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-00711			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen Sodium			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299135	EXPEDITED (15-DAY)		OT	CA-ROCHE-2523802		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide [Indapamide]			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naprosyn [Naproxen]			C				Not Reported
	Prednisone			C				Not Reported
	Ramipril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299166	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Ciclosporin	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299217	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524271		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug-Induced Liver Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299224	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524708		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Extremity Contracture; Psoriasis; Pustular Psoriasis;	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Rheumatoid Arthritis; Scar	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Orencia	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Synthroid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299249	EXPEDITED (15-DAY)		HO	CA-ROCHE-2524262		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Cyst; Crohn'S Disease; Deafness Neurosensory; Deformity; Diarrhoea; Drug Ineffective; Dry Eye; Exostosis; Fatigue; Hypersensitivity; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Osteoarthritis; Osteopenia;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased	Oxycontin	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299256	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524986		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299262	EXPEDITED (15-DAY)		OT	CA-ROCHE-2526036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299293	EXPEDITED (15-DAY)		OT	CA-ROCHE-2525016		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depomedrol			C	Other			Not Reported
	Depomedrol			C	Other	Suspension Intraarticular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299298	EXPEDITED (15-DAY)		OT	CA-ROCHE-2525970			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Leukopenia; Nephrolithiasis; Product Dose Omission; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299316	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527290		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299340	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527566			Female	CAN

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

Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299342	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527555			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299373	EXPEDITED (15-DAY)		HO	CA-ROCHE-2527572		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine	Actemra			S	Intravenous (not			Not Reported

Increased			otherwise specified)		
	Apo-Gabapentin	S	Oral		Not Reported
	Celebrex	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Fentanyl	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	Solution	Not Reported
	Myochrysine	S	Intramuscular	Solution Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycontin	S	Unknown	Tablet (Extendedrelease)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Actonel	C	Unknown		Not Reported
	Diphenoxylate Hydrochloride	C	Unknown		Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown		Not Reported
	Ergocalciferol	C	Intravenous (not otherwise specified)		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Loperamide Hydrochloride	C	Unknown		Not Reported
	Nasonex	C	Unknown	Spray, Metered Dose	Not Reported
	Oxycodone Terephthalate	C			Not Reported
	Pantoprazole Magnesium	C	Unknown	Tablet (Entericcoated)	Not Reported
	Prednisone	C	Unknown		Not Reported
	Trazodone Hydrochloride	C	Oral		Not Reported
	Tylenol	C	Oral		Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299384	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527568		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299400	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527965		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299443	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527587		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17299448	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527600		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celecoxib			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	12681997	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016400589		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Contraindicated Product Administered; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Celecoxib			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	500 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5.0 Milligram, Bid		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	10 Mg/Kg, Weekly		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk (Powder For Solution)		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk (Solution)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo Celecoxib			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	2 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Sulfate] Hydromorphone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	13188251	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2017GMK026180			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Arthralgia; Asthenia; Diarrhoea; Fatigue; Hernia; Pneumonia; Presyncope; Rheumatoid Arthritis	Gabapentin			S	Unknown	Unk		Glenmark
	Esomeprazole Magnesium			S	Oral	40 Mg, Od (1 Every 1 Day)		Not Reported
	Folic Acid			S	Unknown	1 Df, 2 Every 1 Week		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid (2 Every 1 Day)		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qw (1 Every 1 Week)		Not Reported
	Prednisone			S	Unknown	5 Mg, Od (1 Every 1 Day)		Not Reported
	Xeljanz			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw (1 Every 1 Week)		Not Reported
	Plaquenil /00072603/			S	Unknown	200 Mg, Bid (2 Every 1 Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	13852885	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070303			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Related Reaction; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Intra-arterial	25 Mg, Qwk	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Mg, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	14507104	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1805859US			Male	CAN

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

Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Asacol 800	S	Oral	800 Mg, Tid	Allergan
	Amlodipine Besylate	S	Oral	5 Mg, Qd	Not Reported
	Amlodipine Besylate	S	Oral	5 Mg, Unknown	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Unknown	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Unknown	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Unknown	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Bi-Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	50 Mg, Q Week	Not Reported
	Plaquenil	S	Unknown	Unk, Unknown	Not Reported
	Humira	S	Subcutaneous	Unk Unk, Unknown	Not Reported
	Orencia	S			Not Reported
	Atacand Plus	C	Oral	Unk	Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Mg, Unknown	Not Reported
	Depo-Medrol	C	Intra-articular	120 Mg, Unknown	Not Reported
	Depo-Medrol	C	Intramuscular	120 Mg, Unknown	Not Reported
	Depo-Medrol	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Oral	300 Mg, Unknown	Not Reported
	Folic Acid	C	Oral	5 Mg, Unknown	Not Reported
	Tylenol	C	Unknown	500 Mg, Unknown	Not Reported
	Vitamin D3	C	Unknown	1000 Iu, Qd	Not Reported
	Amlodipine Besilate	C	Oral	5 Mg, Unk	Not Reported
	Omega Allergenic Extracts	C		1 Df, Qd Intradermal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	14678468	EXPEDITED (15-DAY)		OT	CA-ROCHE-2089917		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Azathioprine		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	15980424	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017430169		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Reaction; Injection Site Urticaria; Nausea; Rash; Urticaria	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Oral	25 Milligram, Qd		Not Reported
	Atenolol			C	Oral	50 Mg, 1x/Day		Not Reported
	Simponi			C		Unk		Not Reported
	Inflectra [Infliximab]			C	Intravenous (not otherwise specified)	300 Milligram,(Q0, 2,6, Week Then Every 8		Not Reported

Weeks

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	16083042	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2706659-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Oral			Not Reported
	Celecoxib			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	16981320	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1128206		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug	Ciprofloxacin Hydrochloride			S	Unknown			Not Reported
	Amoxicillin Sodium And Clavulanate Potassium			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva

Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Clavulin	S	Unknown		Not Reported
	Hydroxychloroquine	C			Not Reported
	Prednisone	C		705 Milligram Daily;	Not Reported
	Prednisone	C	Unknown	7.5 Milligram Daily;	Not Reported
	Tridural	C	Unknown		Not Reported
	Tylenol[Paracetamol]	C	Unknown		Not Reported
	Plaquenil[Hydroxychloroquine Phosphate]	C		400 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17282858	EXPEDITED (15-DAY)		OT	NVSC2020US008551			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Dermatitis	Hydroxychloroquine Sulfate			S	Oral	2 Df, Qd		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17288297	EXPEDITED (15-DAY)		OT	CA-ROCHE-2522989		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea;	Rituximab			S	Unknown			Not Reported

Renal Mass; Vomiting	Azathioprine	S	Unknown	Not Reported
	Cyclosporin A	S	Unknown	Not Reported
	Depo-Provera	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Naprosyn [Naproxen]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17295895	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524847		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Swelling; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution For Infusion		Not Reported
	Arava			S	Oral			Not Reported
	Benzylpenicillin			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)		
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution For Infusion	Not Reported
	Rocuronium Bromide	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sulfamethoxazole/Trimethoprim	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Solution	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17295928	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202001000290			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dry Skin; Rash Erythematous; Skin Burning Sensation; Skin Exfoliation	Hydroxychloroquine			S		Unk		Concordia
	Dupixent			C		600 Mg (Loading Dose)		Not Reported
	Dupixent			C		300 Mg, (Every 2 Weeks)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17296360	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527559		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported

	Leucovorin [Folinic Acid]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17296373	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524696			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17297000	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202001000297			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Unexpected	Hydroxychloroquine			S		200 Mg, Qd		Concordia
	Citracal Max			S		315 Mg + 250iu, Tid		Not Reported
	Cephalexin			S		250 Mg, Qid		Not Reported
	Diltiazem			S		120 Mg, Qd		Not Reported
	Diltiazem			S		300 Mg, Qd		Not Reported
	Furosemide			S		60 Mg, Qd (Morning)		Not Reported
	Furosemide			S		40 Mg, Qd (Afternoon)		Not Reported
	Esopmeprazole			S		40 Mg, Bid		Not Reported
	Potassium Chloride Er			S		10 Meq, Bid		Not Reported
	Prednisone			S		5 Mg, Qd		Not Reported
	Dofetilide			S		0.25 Mg, Bid		Not Reported
	Dofetilide			S				Not Reported
	Trazodone			S		375 Mg, Qd (Bedtime)		Not Reported
	Warfarin			S		5 Mg, Qd		Not Reported
	Warfarin			S		2.5 Mg, (Monday, Wednesday, And Friday)		Not Reported
	Alendronate			S		70 Mg, Weekly		Not Reported
	Diphenoxylate-Atrop			S		10 Mg, Prn, Daily		Not Reported
	Tracleer			S	Oral	125 Mg, Bid		Not Reported
	Zydus Bosentan			S	Oral	125 Mg, Qd		Not Reported
	Finasteride			S		5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17297030	EXPEDITED (15-DAY)		OT	CA-ROCHE-2523731		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Ineffective; Nausea; Synovitis; Tachycardia			otherwise specified)		
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17297592	EXPEDITED (15-DAY)		HO	CN-ROCHE-2525198		24 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Intentional Product Use Issue; Myocardial Necrosis Marker Increased; Off Label Use	Cellcept [Mycophenolate Mofetil]			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methylprednisolone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17297685	EXPEDITED (15-DAY)		OT	CA-LUPIN HEALTHCARE (UK) LIMITED-2020-00237		43 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Dyspnoea; Rash	Cephalexin			S	Unknown	Unk		Lupin
	Erythromycin			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk (Solution Subcutaneous)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17298570	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-06970			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Diarrhoea; Muscle Spasms; Pruritus; Urticaria	Duloxetine			S	Unknown	Unk		Lupin
	Sertraline			S	Unknown	Unk		Lupin
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Lupin
	Oxycodone			S	Unknown	Unk		Novel Labs

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17298582	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08449		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Retinopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose: 1952 Grams)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17299424	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020027146		41 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinitis	Triatec (Ramipril)			S	Oral	1 Df, Qd		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	1tab 2/2d + 2tab 2/2d		Not Reported
	Cortancyl			S	Oral	1 Df, Qd		Not Reported
	Uvedose			S	Oral	1 Df, Q3m		Not Reported
	Dafalgan Codeine			S	Oral	4 Df, Qd		Not Reported
	Calcidose [Calcium Carbonate]			S	Oral	2 Df, Qd		Not Reported
	Advagraf			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17301049	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020027578			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Methotrexate Sodium			S		Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day (2 Every 1 Days)		Pfizer
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17301248	EXPEDITED (15-DAY)		OT	NVSC2020CA013507			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Atypical Mycobacterial Infection; Bacterial Infection; Bronchiectasis; C-Reactive Protein Increased; Cellulitis; Chest Pain; Cough; Crystal Arthropathy; Diarrhoea; Drug Ineffective; Drug Intolerance; Erythema; Gout; Grip Strength Decreased; Infective Exacerbation Of Bronchiectasis; Ligament Sprain; Lung Disorder; Middle Lobe Syndrome; Nightmare; Oropharyngeal Pain; Osteoarthritis; Pain; Paraesthesia; Peripheral Swelling; Rash; Rheumatoid Arthritis;	Azithromycin			S	Unknown			Novartis
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Depomedrol			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Unk (200 Mg Od)		Not Reported

Rheumatoid Factor; Synovitis; Underweight; Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302257	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014160		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia Areata; Arthralgia; Diarrhoea	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qod		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Subcutaneous	15 Mg, Qw		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	300 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302262	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013865			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Somnolence; Visual Impairment	Plaquenil			S		2 Df, Qd; 200 Mg		Sanofi
	Paracetamol			S				Not Reported
	Leflunomide			S	Oral	1 Df, Qd		Sanofi
	Hydroxychloroquine Sulfate			S		2 Df, Qd (200 Mg)		Sanofi
	Sulfasalazine			S				Not Reported
	Paracetamol			S				Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S		1 Df, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Acetaminophen;Codeine Phosphate	C		Not Reported
	Leflunomide	C	Oral	Not Reported
	Meloxicam	C		Not Reported
	Methotrexate	C		Not Reported
	Synthroid	C		Not Reported
	Tylenol W/Codeine No. 3	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302264	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013796			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava			S	Unknown	Unk		Sanofi
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Prednisone			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported

	Actemra		S	Unknown	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302271	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014594			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Sanofi
	Enbrel			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302275	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014506			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Swelling	Arava			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302291	EXPEDITED (15-DAY)		OT	JP-MYLANLABS-2020M1007334			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Prednisolone			S	Oral	20 Milligram, Qd		Not Reported

Prednisolone	S	Oral	60 Milligram, Qd		Not Reported
Mycophenolate Mofetil	S	Unknown			Not Reported
Tacrolimus	S	Unknown			Mylan
Hydroxychloroquine	S	Unknown			Mylan
Cyclophosphamide	S	Unknown	Pulse Therapy		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302530	EXPEDITED (15-DAY)		OT	RU-ASTRAZENECA-2019SF30946			Female	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Premature Delivery	Omeprazole			S	Oral			Not Reported
	Acyclovir			S	Unknown			Not Reported
	Chloropyramine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Igg			S	Intravenous (not otherwise specified)			Not Reported
	Nadroparin			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Rituximab			S	Unknown	2 Infusions 14-21 Days Apart Of 1000mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302578	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1006250		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Doxycycline			S	Oral	200 Milligram, Qd		Not Reported
	Silodyx			S	Oral	Unk		Mylan
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17303675	EXPEDITED (15-DAY)		DE	CA-009507513-2001CAN007751		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Alendronate Sodium			S	Unknown	70 Milligram, Qw		Merck
	Flovent			S	Unknown			Not Reported
	Albuterol Sulfate (+) Ipratropium Bromide			S	Unknown			Not Reported
	Lasix (Furosemide Sodium)			S	Unknown	40 Milligram		Not Reported
	Lipitor			S	Unknown	10 Milligram		Not Reported
	Losec (Omeprazole Magnesium)			S	Oral	20 Milligram		Not Reported
	Metformin			S	Unknown	500 Milligram, Bid		Not Reported
	Nitrazadon			S	Unknown	10 Milligram		Not Reported
	Plaquenil			S	Unknown	300 Milligram, Qd		Not Reported
	Prednisone			S		5 Milligram, Qd		Not Reported
	Salmeterol Xinafoate			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	500 Milligram		Not Reported
	Atorvastatin Calcium			S	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17304866	EXPEDITED (15-DAY)		DE	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Combivent			S	Unknown			Boehringer Ingelheim
	Alendronate Sodium			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Lasix [Furosemide]			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported

Losec [Omeprazole]	S	Unknown		Not Reported
Metformin	S	Unknown		Not Reported
Nitrazadon	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Salmeterol Xinafoate	S	Unknown		Not Reported
Tylenol	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17305041	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2020CA017795			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Creatinine Urine Abnormal; Cutaneous Sarcoidosis; Drug Ineffective; End Stage Renal Disease; Ocular Sarcoidosis; Proteinuria; Pulmonary Sarcoidosis	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	14849864	EXPEDITED (15-DAY)		CA, OT	CA-ROCHE-2114741		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness;	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	15263337	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-021076		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Conduction Disorder; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Mental Status Changes; Overdose; Sinus Tachycardia; Ventricular Tachycardia	Hydroxychloroquine			S	Oral			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	16167858	NON-EXPEDITED			US-AMGEN-USASP2019053482		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Allopurinol			S	Unknown	Unk		Not Reported

	Macrobid [Clarithromycin]		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	16468077	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-211285		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningitis; Parkinsonism; Seizure	Hydroxychloroquine			S	Unknown	Unk		Sun
	Methotrexate			S	Unknown	Unk		Sun
	Prednisone			S	Unknown	10 Milligram, Daily		Mutual

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	16607608	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-040844		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Cephalexin Tablets			S	Unknown	Unk		Aurobindo
	Ciprofloxacin			S	Unknown	Unk		Aurobindo
	Clindamycin			S	Unknown	Unk		Aurobindo
	Losartan			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Avelox			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enalapril			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported

	Hctz	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Penicillin G	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Cipro	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Intracardiac	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17002086	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091594		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	300 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17097307	NON-EXPEDITED		HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2019-07074		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Dizziness; Overdose	Hydroxychloroquine Sulfate Tablets			S	Oral	20 Dosage Form, Single		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17133380	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP025719		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Therapeutic Product Effect Incomplete	Rabeprazole			S	Unknown	20 Mg, Unk		Apotex
	Prednisone			S	Unknown	15 Mg, Unk		Not Reported
	Meloxicam			S	Unknown	15 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Desoximetasone			S	Unknown	13 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17157820	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP025989		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product	Metformin			S	Unknown	Unk		Apotex
	Metformin			S				Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder; Weight Increased	Cymbalta	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Imuran /00001501/	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Xarelto	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17161620	NON-EXPEDITED		OT	TN-LUPIN PHARMACEUTICALS INC.-2019-06882		50 YR	Female	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	200 Milligram, Qd (Daily Dose Of 3 Mg/Kg/Day With A Cumulative Dose Of 730 Gram)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17241172	EXPEDITED (15-DAY)		OT	GB-ADVANZ PHARMA-201912003257			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea; Lower Respiratory Tract Infection; Oropharyngeal Pain; Wheezing	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Kevzara			S	Subcutaneous	200 Mg Qow, Every Other Week		Not Reported
	Sarilumab Pre-Filled Syringe			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17305033	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013889			Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rash; Rheumatoid Arthritis	Plaquenil	S		400 Mg	Sanofi
	Leflunomide	S		20 Mg	Sanofi
	Methotrexate	S	Oral	20 Mg	Not Reported
	Sulfasalazine	S		500 Mg	Not Reported
	Actemra	S			Not Reported
	Enbrel	S			Not Reported
	Orencia	S			Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17305038	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013783			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Deformity; Finger Deformity; Foot Deformity; Hand Deformity; Hepatic Failure; Hypersensitivity; Infection; Knee Arthroplasty; Ocular Icterus; Osteoarthritis; Pain; Pancreatitis; Upper Limb Fracture; Wrist Deformity	Arava			S				Sanofi
	Celecoxib			S		Unk		Not Reported
	Diclofenac Sodium			S				Not Reported
	Plaquenil			S				Sanofi
	Sulfasalazine			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Methotrexate			C	Subcutaneous	5 Mg, Qw		Not Reported
	Xeljanz			C		5 Mg, Qod		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17305039	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA013785		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Leflunomide			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown			Sanofi
	Methotrexate			S	Unknown	15 Mg/M2, Qw		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S				Not Reported

	Humira	S	Subcutaneous	4 Mg, Qw	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	200 Mg, Qm	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Unknown	42 Mg	Not Reported
	Tocilizumab	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17305448	NON-EXPEDITED			US-AMCO LTD-GSH201611-005903			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Hydralazine			S	Unknown	25 Mg, Tid		Not Reported
	Azathioprine			S	Unknown	50 Mg, Tid		Not Reported
	Prednisone			S	Unknown	40 Mg, Qd		Not Reported
	Prednisone			S	Unknown	100 Mg, Qd		Not Reported
	Prednisone			S				Not Reported
	Furosemide			S	Intravenous drip	80 Mg, Qd		Not Reported
	Furosemide			S	Unknown	80 Mg, Freq: Unk X 1 Days		Not Reported
	Carvedilol			S	Oral	12.5 Mg, Tid		Not Reported
	Isosorbide Mononitrate			S	Unknown	Unk		Not Reported
	Nitroglycerine			S	Intravenous (not otherwise specified)	60 Mg, Qd		Not Reported
	Methylprednisolone			S	Unknown	250 Mg, Qid (Q6h)		Not Reported
	Methylprednisolone			S				Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Cyclophosphamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17305695	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS		25 YR	Female	USA

INC.-2019-08485

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose: 730 Grams)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17305711	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08484		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose: 1314 Grams)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17305748	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0480		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Hypogammaglobulinaemia; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17306364	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-003471		61 YR	Female	CAN

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

Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Alendronic Acid	S	Unknown	Unk		Aurobindo
	Actemra	S	Unknown	Unk		Not Reported
	Asa	S	Unknown	Unk		Not Reported
	Calcium	S	Unknown	Unk		Not Reported
	Fosinopril	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Morphine	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Simponi	S	Unknown	Unk		Not Reported
	Synthroid	S	Unknown	Unk		Not Reported
	Tylenol	S	Unknown	Unk		Not Reported
	Vitamin D	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17306510	EXPEDITED (15-DAY)		DE	US-PERRIGO-20US000826		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Clindamycin Palmitate Hydrochloride			S	Oral	Unknown, Unknown		Perrigo
	Esomeprazole Magnesium			S	Oral	Unknown, Unknown		Perrigo
	Hydroxychloroquine			S	Oral	Unknown, Unknown		Not Reported
	Cyclobenzaprine			S	Oral	Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17306659	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004089		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb

Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Actemra	S	Subcutaneous	Unk	Not Reported
	Alendronate Sodium	S	Oral		Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, Qd	Not Reported
	Prednisone	S	Oral		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Q12h	Not Reported

Sulfasalazine	S	Oral	500 Milligram		Not Reported
Sulfathalidine	S	Oral	1000 Milligram, Q12h		Not Reported
Sulfathalidine	S	Oral	500 Milligram		Not Reported
Tofacitinib	S	Unknown	5 Milligram, Q12h		Not Reported
Tofacitinib Citrate	S	Unknown	5 Milligram, Q12h		Not Reported
Topicort [Desoximetasone]	S	Cutaneous	Unk		Not Reported
Atasol [Paracetamol]	C	Unknown			Not Reported
Salazopyrin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307005	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2020-003529		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Alendronic Acid Tablets			S	Oral	Unk		Aurobindo
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hcl / Pseudoephedrine Hcl			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400.0 Milligram, Once A		Not Reported

			Day	
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	20 Milligram, Once A Day	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	400 Milligram, Once A Day	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Two Times A Day	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfathalidine	S	Oral	1000 Milligram, Two Times A Day	Not Reported
Sulfathalidine	S	Oral	500 Milligram	Not Reported
Tofacitinib	S	Unknown	5 Milligram, Two Times A Day	Not Reported
Tofacitinib Citrate	S	Unknown	5 Milligram, Two Times A Day	Not Reported
Topicort	S	Cutaneous	Unk	Not Reported
Atasol	C	Unknown	Unk	Not Reported

	Salazopyrin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307010	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-003544			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Topical	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Folic Acid			S	Subcutaneous	1.0 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Topicort			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307033	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08488		62 YR	Female	USA

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

Retinopathy	Hydroxychloroquine		S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose:1752 Grams)	Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307035	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08481		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maculopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose: 1022 Grams)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307037	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08486		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose: 1168 Grams)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307039	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08487		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose: 3796 Grams)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307242	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013790			Female	CAN

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

Drug Ineffective; Hepatic Steatosis; Synovitis	Leflunomide		S	Unknown		Sanofi
	Hydroxychloroquine		S	Unknown	Unk	Sanofi
	Methotrexate		S	Unknown	7.0 Years	Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Orencia		S	Unknown		Not Reported
	Remicade		S	Unknown		Not Reported
	Actemra		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307244	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014596			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Qd (Tablet)		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Acetaminophen			C				Not Reported

	Acetaminophen	C		Unk	Not Reported
	Desoximetasone	C			Not Reported
	Desoximetasone	C		Unk	Not Reported
	Naproxen	C			Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Rabeprazole	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307257	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA013864		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Actemra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C		5 Mg, Qd		Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307302	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013973			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported

Decreased	Actemra	S	Subcutaneous	Unk	Not Reported
	Bacitracin/ Neomycin/ Polymyxin B	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Prednisone	C	Intramuscular	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307308	EXPEDITED (15-DAY)		LT	CA-ROCHE-2527074			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S				Not Reported

	Sulfate]				
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S			Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307513	EXPEDITED (15-DAY)		OT	IT-LAURUS LABS LIMITED-201900430		72 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Malaise; Off Label Use; Pain; Papule; Pyrexia; Skin Lesion	Hydroxychloroquine Sulfate			S	Unknown	Two Daily Doses		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Amlodipine			C	Unknown	Daily		Not Reported
	Acetylsalicylic Acid			C	Unknown	Lunchtime		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307544	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08489		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose: 1460 Grams)		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307546	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-08482		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	5.44 Milligram/Kilogram, Qd, (Total Dose: 2044		Lupin

Grams)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307555	NON-EXPEDITED		OT	TR-LUPIN PHARMACEUTICALS INC.-2019-08628		64 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Methylprednisolone			S	Unknown	40 Milligram, Qd		Lupin
	Methylprednisolone			S	Unknown	120 Milligram, Qd		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307572	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524920			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn [Naproxen]			S	Oral			Not Reported
	Naprosyn [Naproxen]			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307577	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1171473		62 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Doxycycline			S	Oral	200 Mg		Actavis
	Silodyx			S	Oral			Not Reported
	Plaquenil			S	Oral	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307592	EXPEDITED (15-DAY)		OT	CA-ROCHE-2525953			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307918	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014608		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	10 Mg		Sanofi
	Hydroxychloroquine			S		200 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S		Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown	50 Mg		Not Reported
	Enbrel			S	Subcutaneous	1 Df, Qw		Not Reported
	Humira			S	Unknown	0.8 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

Rituxan	S	Unknown		Not Reported
Rituxan	S	Unknown		Not Reported
Rituximab	S			Not Reported
Rituximab	S			Not Reported
Rituximab;Urelumab	C			Not Reported
Simponi	C	Subcutaneous		Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307937	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013792			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg		Sanofi
	Methotrexate			S	Unknown	17.5 Mg, Qw		Not Reported
	Actemra			S	Subcutaneous	162 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg		Not Reported
	Rituximab			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307951	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-233921		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Exposure During Pregnancy; Stillbirth	Dexamethasone			S	Unknown	Unk		Sun
	Prednisone			S	Unknown	Unk		Mutual
	Methylprednisolone			S	Unknown	Unk		Not Reported

	Plaquenil	S	Unknown	Unk		Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported
	Etoposide	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17307955	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-233323		42 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Cardiotoxicity; Restrictive Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17308071	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013870			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Arava			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	Unk, Qw		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17309844	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524259			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Depo-Medrol			C	Unknown	Suspension Intraarticular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Humira			C	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17309928	EXPEDITED (15-DAY)		HO	CA-ROCHE-2527599		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrochlorothiazide			S	Oral			Not Reported

	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Atenolol	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17309967	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527606		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310017	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527625		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310041	EXPEDITED (15-DAY)			US-ROCHE-2271070			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash	Rituxan			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310141	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527871			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310170	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527907		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Rash; Rheumatoid Arthritis; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310171	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527945			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310198	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528070		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Septra			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310227	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528042			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Meloxicam	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310389	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528362			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310466	EXPEDITED (15-DAY)		HO	CA-ROCHE-2528420			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Hydroxychloroquine		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Cymbalta		C	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310502	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528462		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Tenderness; Adverse Drug Reaction; Arthralgia; Arthropathy; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310532	EXPEDITED (15-DAY)		OT	CA-ROCHE-2529940		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310558	EXPEDITED (15-DAY)		HO	US-ROCHE-2281337		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Gastroenteritis Salmonella; Post Procedural Infection	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310583	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530230		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Celebrex			C	Unknown			Not Reported
	Cimzia			C	Subcutaneous	Solution Subcutaneous Single Use		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310605	EXPEDITED (15-DAY)		OT	CA-009507513-2001CAN007489		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered;	Fosamax			S	Unknown	Unk		Merck
	Golimumab			S	Unknown	Unk		Merck

Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Prednisone	S	Unknown	Unk	Merck
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Merck
	Actemra	S	Unknown	Unk	Not Reported
	Apo Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride (+) Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	5.0 Milligram	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Formulation: Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20.0 Milligram, Qd (1 Every 1 Day)	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S	Oral	25 Milligram; Solution	Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400.0 Milligram, Qd (1 Every 1 Day)	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported

	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine		S	Oral	1000.0 Milligram, Bid (2 Every 1 Day)	Not Reported
	Sulfathalidine		S	Unknown	Unk	Not Reported
	Diclofenac		C	Unknown	Unk	Not Reported
	Salazopyrin		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310626	EXPEDITED (15-DAY)		HO	US-ROCHE-2460671		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fungal Infection	Rituximab			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310662	EXPEDITED (15-DAY)			US-ROCHE-2288732			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Drug Ineffective	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Cimzia	S	Unknown		Not Reported
	Kevzara	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310755	EXPEDITED (15-DAY)			US-ROCHE-2260871			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Rituxan			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310797	EXPEDITED (15-DAY)			US-ROCHE-2262800			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17310926	EXPEDITED (15-DAY)		HO	US-ROCHE-2344654		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningoencephalitis Viral; West Nile Viral Infection	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfamethoxazole/Trimethoprim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17311279	EXPEDITED (15-DAY)			US-ROCHE-2253451			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Rituximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz Xr			C	Oral	30 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17311283	EXPEDITED (15-DAY)		HO	US-ROCHE-2249579		53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Mycobacterial Infection; Pneumocystis	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported

Jirovecii Pneumonia	Adalimumab	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Azathioprine	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Sulfamethoxazole/Trimethoprim	C	Oral	As Prophylaxis	Not Reported
	Sulfamethoxazole/Trimethoprim	C	Oral	High Dose As 21-Day Treatment Course For P. Jirovecii Pneumonia	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17311445	EXPEDITED (15-DAY)			US-ROCHE-2317551			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Drug Ineffective	Rituxan			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17311504	EXPEDITED (15-DAY)		OT	US-ROCHE-2329821		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Rituximab			S	Intravenous drip	Single Dose		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	For 5 Days		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Cyclophosphamide			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Enoxaparin			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17311593	EXPEDITED (15-DAY)			US-ROCHE-2247406			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Vomiting	Rituximab			S	Unknown	4 Months		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Unknown	10 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral	30 Days, 11 Refills		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17311655	EXPEDITED (15-DAY)			US-ROCHE-2269536			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Jan-2020	17312691	EXPEDITED (15-DAY)		DE	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Combivent			S	Unknown			Boehringer Ingelheim
	Alendronate Sodium			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Lasix [Furosemide]			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Losec [Omeprazole]			S	Oral			Not Reported
	Metformin			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	12913307	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091228		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported

Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Bid	Not Reported
	Humira	S	Subcutaneous	40 Milligram Cyclical	Not Reported
	Humira	S	Subcutaneous	40 Gram	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Parenteral	Unk	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2000 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	2000 Milligram	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2 Every 1 Day	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Imuran [Azathioprine Sodium]	S	Unknown	Unk	Not Reported
	Plaquenil S	S	Unknown		Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Other	Unk	Not Reported
	Tofacitinib	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	15705980	EXPEDITED (15-DAY)		OT	CA-009507513-1812CAN000060			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Fosamax			S	Unknown	Unk Unk, Unknown		Merck
	Cozaar			S	Unknown	Unk Unk, Unknown		Merck
	Cozaar			S	Unknown	Unk Unk, Unknown		Merck
	Vasotec			S	Unknown	Unk		Merck
	Vasotec			S		Unk		Merck
	Methotrexate			S	Subcutaneous	10 Milligram, Qw (Qwk)		Not Reported
	Methotrexate			S	Subcutaneous	10 Miligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Biaxin			S	Unknown	Unk, Unknown		Not Reported
	Celebrex			S	Unknown	Unk, Unknown		Not Reported
	Ciprofloxacin			S	Unknown	Unk Unk, Unknown		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Clindamycin			S	Unknown	Unk, Unknown		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qw		Not Reported
	Enbrel			S		Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk Unk, Unknown		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk Unk, Unknown		Not Reported
	Hydralazine Hydrochloride			S	Unknown	Unk		Not Reported
	Keflex			S	Unknown	Unk Unk, Unknown		Not Reported
	Levaquin			S	Unknown	Unk		Not Reported
	Metoprolol Tartrate			S	Unknown	Unk		Not Reported
	Moxifloxacin Hydrochloride			S	Unknown	Unk Unk, Unknown		Not Reported

Moxifloxacin Hydrochloride	S	Unknown	Unk Unk, Unknown	Not Reported
Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
Pariet	S	Unknown	Unk, Unknown	Not Reported
Penicillin (Unspecified)	S	Unknown	Unk Unk, Unknown	Not Reported
Plaquenil	S	Unknown	Unk, Unknown	Not Reported
Cephalexin	S	Unknown		Not Reported
Diazide (Gliclazide)	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Isoniazid	S	Unknown		Not Reported
Lopressor	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Penicillin G	S	Unknown		Not Reported
Tecta	S	Unknown		Not Reported
Xeljanz	S		50 Milligram, 2 Every 1 Day(S)	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	8.5 Milligram, Every Day	Not Reported
Venofer	C		Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C		Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Cipro (Ciprofloxacin)	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Iron Sucrose	C	Unknown		Not Reported
Atenolol	C			Not Reported
Colchicine	C			Not Reported
Coversyl (Perindopril Erbumine)	C			Not Reported
Leucovorin	C			Not Reported
Levothyroxine Sodium	C			Not Reported
Ranitidine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	15978307	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013831		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk Unk, Qmo		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	400 Mg, Unk		Not Reported
	Asa			C	Unknown	81 Mg, Unk		Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide [Indapamide]			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	16199338	EXPEDITED (15-DAY)		OT	CA-009507513-1904CAN006094		44 YR	Female	CAN

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

Abdominal Pain; Antinuclear Antibody Positive; Arthralgia; Atelectasis; Bursitis; Conjunctivitis; Contraindicated Product Administered; Crepitations; Cushingoid; Drug Ineffective; Dry Eye; Dry Mouth; Dyspnoea; Erythema; Eye Irritation; Eye Pain; Feeling Jittery; Fibromyalgia; Flank Pain; Haemoglobin Decreased; Impaired Work Ability; Infection; Interstitial Lung Disease; Joint Effusion; Joint Swelling; Lung Disorder; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neoplasm Malignant; Nodule; Ocular Hyperaemia; Pain; Pain In Extremity; Peripheral Swelling; Photophobia; Pleuritic Pain; Pneumonia; Pruritus; Rash; Red Blood Cell Count Decreased; Rheumatoid Arthritis; Rheumatoid Nodule; Scleritis; Swelling Face; Synovial Cyst; Synovial Fluid Analysis; Tenderness; Tenosynovitis Stenosans; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Thrombosis; Ulcer; Visual Impairment; Wheezing	Fosamax	S	Unknown	Unk	Merck
	Acetaminophen	S	Unknown	Dosage Form: Not Specified	Not Reported
	Acetaminophen (+) Oxycodone Hydrochloride	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Alendronic Acid	S	Unknown	Unk	Not Reported
	Amitriptyline Pamoate	S	Oral	75.0 Milligram, 1 Every 1 Day (S)	Not Reported
	Amitriptyline Pamoate	S	Oral	75 Milligram, 1 Every 24 Hours	Not Reported
	Apo Amitriptyline	S	Oral	75 Milligram, 1 Every 1 Days	Not Reported
	Apo Amitriptyline	S	Unknown	Unk	Not Reported
	Apo Amitriptyline	S	Oral	75 Milligram, 1 Every 1 Day (S)	Not Reported
	Apo Amitriptyline	S	Oral	75 Milligram, 1 Every 24 Hours	Not Reported
	Apo Amitriptyline	S	Oral	75 Milligram, 1 Every 24 Hours	Not Reported
	Apo-Meloxicam	S	Unknown	150 Milligram, 1 Every 1 Day (S)	Not Reported
	Apo-Meloxicam	S	Unknown	150 Milligram, 1 Every 24 Hours	Not Reported
	Apo-Meloxicam	S	Unknown	Unk	Not Reported
	Apo Naproxen	S	Oral	500 Milligram, 1 Every 1 Day (S)	Not Reported
	Apo Naproxen	S	Oral	250 Milligram, 2 Every 1 Day (S)	Not Reported
	Apo Naproxen	S	Oral	1000.0 Milligram, 1 Every 1 Day (S)	Not Reported
	Apo Naproxen	S	Oral	250 Milligram, 2 Every 1 Day (S)	Not Reported
	Apo Naproxen	S	Oral	1000 Milligram, 1 Every 1	Not Reported

			Day (S)	
Apo Naproxen	S	Oral	500 Milligram, 2 Every 1 Days	Not Reported
Apo Naproxen	S	Oral	500 Milligram, 2 Every 1 Days	Not Reported
Apo Naproxen	S	Oral	1000 Milligram, 1 Every 24 Hours	Not Reported
Apo Naproxen	S	Oral	500 Milligram, 1 Every 24 Hours	Not Reported
Apo Naproxen	S	Oral	500 Milligram, 1 Every 12 Hours	Not Reported
Apo Prednisone	S	Unknown	15 Milligram, 1 Every 1 Day	Not Reported
Apo Prednisone	S	Unknown	Unk	Not Reported
Apo Prednisone	S	Unknown	150 Milligram, 1 Every 24 Hours	Not Reported
Apo Prednisone	S	Unknown	15 Milligram, 1 Every 24 Hours	Not Reported
Apo Prednisone	S		Unk	Not Reported
Apo Ranitidine	S	Oral	300 Milligram, 1 Every 1 Day (S)	Not Reported
Apo Ranitidine	S	Oral	150 Milligram, 2 Every 1 Day (S)	Not Reported
Apo Ranitidine	S	Unknown	150 Milligram, 2 Every 1 Days	Not Reported
Apo Ranitidine	S	Unknown	Unk	Not Reported
Apo Ranitidine	S	Oral	300 Milligram, 1 Every 24 Hours	Not Reported
Apo Ranitidine	S	Oral	300 Milligram, 1 Every 1 Week	Not Reported
Apo Ranitidine	S	Oral	300 Milligram, 1 Every 24 Hours	Not Reported
Apo Ranitidine	S	Oral	150 Milligram, 2 Every 1 Days	Not Reported

Bactrim	S	Unknown	Dosage Form: Not Specified	Not Reported
Depo-Medrol	S	Intra-articular	Suspension Intra-Articular	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, 1 Every 1 Weeks	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, 1 Every Weeks	Not Reported
Enbrel	S	Subcutaneous	50 Milligram 1 Every 1 Week	Not Reported
Enbrel	S	Subcutaneous	50 Milligram	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Enbrel	S		Unk	Not Reported
Esomeprazole Magnesium (+) Naproxen	S	Oral	Unk	Not Reported
Esomeprazole Magnesium (+) Naproxen	S	Unknown	Unk	Not Reported
Esomeprazole Sodium	S	Unknown	Unk	Not Reported
Esomeprazole Sodium	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	40.0 Milligram, Dosage Form: Solution Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Imuran (Azathioprine Sodium)	S	Unknown	150 Milligram, 2 Every 1 Day	Not Reported
Imuran (Azathioprine Sodium)	S	Unknown	150 Milligram, Dosage Form: Not Specified	Not Reported
Lyrica	S	Oral	150 Milligram, 2 Every 1 Day(S)	Not Reported
Lyrica	S		300 Milligram, 1 Every 1 Days	Not Reported
Lyrica	S	Oral	300 Milligram, 1 Every 24 Hours	Not Reported
Methotrexate	S	Oral	20 Milligram, 1 Every 1 Weeks	Not Reported

Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Oral	20 Milligram	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methylprednisolone Acetate	S	Intra-articular	Unk	Not Reported
Methylprednisolone Acetate	S	Unknown	Unk	Not Reported
Mobicox	S	Oral	Unk	Not Reported
Pantoloc	S	Oral	Dosage Form: Tablet (Enteric Coated)	Not Reported
Pantoprazole	S	Oral	Unk	Not Reported
Pantoprazole	S	Unknown	Unk	Not Reported
Pregabalin	S	Oral	300 Milligram, 1 Every 1 Day(S)	Not Reported
Pregabalin	S	Oral	150 Milligram, 2 Every 1 Days	Not Reported
Pregabalin	S	Oral	300 Milligram, 1 Every 24 Hours	Not Reported
Septra	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, 1 Every 1 Day(S), Dosage Form: Not Specified	Not Reported
Sulfasalazine	S	Oral	1 Gram, 1 Every 1 Days	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, 1 Every 1 Week	Not Reported
Sulfasalazine	S	Oral	1 Gram, 1 Every 24 Hours	Not Reported
Sulfasalazine	S	Oral	1 Gram, 1 Every 24 Hours	Not Reported
Oxycocet	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	15.0 Milligram, 1 Every 1 Day	Not Reported
Prednisone	S	Unknown	150 Milligram, 1 Every 1 Days	Not Reported

Prednisone	S	Oral	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	15 Milligram, 1 Every 24 Hours	Not Reported
Ranitidine	S	Oral	300 Milligram, 1 Every 1 Day	Not Reported
Ranitidine	S	Oral	150 Milligram, 2 Every 1 Days	Not Reported
Ranitidine	S	Oral	300 Milligram, 1 Every 1 Week	Not Reported
Ranitidine	S		300 Milligram, 1 Every 1 Days	Not Reported
Ranitidine	S	Oral	150 Milligram, 1 Every 12 Hours	Not Reported
Ranitidine	S	Oral	300 Milligram, 1 Every 24 Hours	Not Reported
Ranitidine	S	Oral	300 Milligram, 1 Every 24 Hours	Not Reported
Tofacitinib Citrate	S	Oral	10 Milligram, 1 Every 1 Day(S)	Not Reported
Tofacitinib Citrate	S	Oral	5 Milligram, 2 Every 1 Days	Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram, 1 Every 24 Hours	Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram, 1 Every 24 Hours	Not Reported
Etanercept	S	Subcutaneous	50 Milligram	Not Reported
Azathioprine	S	Unknown	150 Milligram	Not Reported
Azathioprine	S	Oral	150 Milligram, 2 Every 1 Days	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	150 Milligram	Not Reported
Amitriptyline Hydrochloride	S	Oral	75.0 Milligram, 1 Every 1	Not Reported

			Day	
Meloxicam	S	Unknown	150 Milligram, 1 Every 1 Days	Not Reported
Meloxicam	S	Unknown	Unk	Not Reported
Meloxicam	S	Unknown	150 Milligram, 1 Every 24 Hours	Not Reported
Trimethoprim	S	Unknown		Not Reported
Xeljanz	S	Oral	10 Milligram, 1 Every 1 Day(S)	Not Reported
Xeljanz	S	Oral	2 Dosage Form, 1 Every 1 Day(S)	Not Reported
Xeljanz	S	Oral	5 Milligram, 2 Every 1 Day(S)	Not Reported
Xeljanz	S	Oral	2 Milligram, 1 Every 1 Days	Not Reported
Xeljanz	S	Oral	2 Milligram, 2 Every 1 Days	Not Reported
Xeljanz	S	Oral	2 Dosage Form, 1 Every 24 Hours	Not Reported
Xeljanz	S	Oral	10 Milligram, 1 Every 24 Hours	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Apo-Alendronate	S	Unknown		Not Reported
Apo Naproxen	S	Unknown	250 Milligram, Bid, Dosage Form: Tablet (Enteric Coated)	Not Reported
Apo Naproxen	S	Unknown	1000 Milligram, 1 Every 1 Days, Dosage Form: Tablet (Enteric Coated)	Not Reported
Apo Naproxen	S	Oral	500 Milligram, 2 Every 1 Days, Dosage Form: Tablet (Enteric Oated)	Not Reported
Elavil Pamoate	S	Oral	75 Milligram, 1 Every 1 Days	Not Reported

Methotrexate	S	Subcutaneous	20 Milligram, 1 Every 1 Weeks, Solution	Not Reported
Methylprednisolone Sodium Succinate	S	Unknown		Not Reported
Methylprednisolone Sodium Succinate	S			Not Reported
Naproxen	S	Oral	500 Milligram, 2 Every 1 Days, Tablet (Enteric Coated)	Not Reported
Naproxen	S	Oral	250 Milligram, 2 Every 1 Days, Tablet (Enteric Coated)	Not Reported
Naproxen	S	Oral	500 Milligram, 1 Every 1 Days	Not Reported
Naproxen	S	Oral	500 Milligram, 2 Every 1 Days	Not Reported
Naproxen	S	Oral	1 Every 1 Days	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S	Oral	1000 Milligram, 1 Every 1 Days	Not Reported
Ratio Oxycocet	S	Unknown	Unk	Not Reported
Sulfamethoxazole (+) Trimethoprim	S	Unknown	Unk	Not Reported
Vimovo	S	Unknown	Tablet (Delayed And Immediate Release)	Not Reported
Amitriptyline Hydrochloride	S		75 Milligram, 1 Every 1 Days	Not Reported
Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Oral	500 Milligram, 2 Every 1 Days	Not Reported
Naproxen Sodium	S	Oral	500 Milligram, 1 Every 1 Days	Not Reported
Naproxen Sodium	S	Oral	250 Milligram, 2 Every 1 Days	Not Reported

Naproxen Sodium	S	Oral	1000 Milligram, 2 Every 1 Days	Not Reported
Naproxen Sodium	S	Oral	1000 Milligram, 1 Every 1 Days	Not Reported
Naproxen Sodium	S	Unknown	1000 Milligram, 1 Every 1 Days	Not Reported
Pantoloc	S	Unknown	Unk	Not Reported
Pantoloc	S	Oral	Unk	Not Reported
Ranitidine Hydrochloride	S	Oral	300 Milligram, 1 Every 1 Days	Not Reported
Vimovo	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Pantoprazole Sodium	S	Oral	Unk	Not Reported
Methotrexate Sodium	S	Oral	20 Milligram, 1 Every 1 Week	Not Reported
Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
Methotrexate Sodium	S		Unk	Not Reported
Pantoloc	S	Unknown	Caoted Tablet	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Dosage Form: Not Specified	Not Reported
Celecoxib	C			Not Reported
Hydroxychloroquine Sulfate	C	Unknown		Not Reported
Plaquenil	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	16199931	EXPEDITED (15-DAY)		DS, HO, OT	CA-009507513-1904CAN006502		54 YR	Female	CAN

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

Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect	Fosamax	S	Unknown	Unk	Merck
	Fosamax	S	Unknown	70 Milligram; 1 Every 1 Week	Merck
	Fosamax	S	Unknown	70 Milligram, 4 Every 1 Week	Merck
	Fosamax	S	Unknown	70 Milligram	Merck
	Actemra	S	Unknown	360.0 Mg, 1 Every Month	Not Reported
	Actemra	S	Unknown	680.0 Mg, 1 Every 4 Weeks	Not Reported
	Actemra	S	Unknown	2.68 Mg, 1 Every 4 Weeks, Dosage Form Reported As Not Specified	Not Reported
	Actemra	S	Unknown	360 Milligram, 1 Every 1 Week	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	25.0 Milligram, 1 In Every 1 Week	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Every 1 Week	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50.0 Milligram	Not Reported
	Enbrel	S	Unknown	25.0 Milligram	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram, Dosage Form Repoted As Subcutaneous Solution	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram, Dosage Form Repoted As Subcutaneous Solution	Not Reported

Decreased; Therapeutic Response Decreased; Tongue Disorder; Ulcer	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	70 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Week, Dosage Form Reported As Not Specified	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	10 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, 1 Every 1	Not Reported

			Week	
Methotrexate	S	Unknown	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 2 Weeks	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	15 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	12 Milligram, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	10 Milligram, 4 Every 1	Not Reported

			Week	
Methotrexate	S	Unknown	12.5 Milligram, 4 Every 1 Week, Dosage Form Reported As Not Specified	Not Reported
Methotrexate	S	Unknown	70 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Unknown	15 Milligram	Not Reported
Methotrexate	S	Unknown	17.5 Milligram	Not Reported
Methotrexate	S	Unknown	12 Milligram	Not Reported
Methotrexate	S	Unknown	10 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram	Not Reported
Methotrexate	S	Unknown	70 Milligram	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 1 Every 1 Week	Not Reported
Myochrysine	S	Parenteral	50 Milligram, 1 Every 1 Month	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, 1 Every 2 Weeks	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, 1 Every 1 Weeks, Dosage Form Reported As Solution Intramuscular	Not Reported
Orencia	S	Unknown	760 Milligram, 1 Every 1 Week	Not Reported
Orencia	S	Unknown	780 Milligram, 1 Every 1 Weeks (Therapy Duration: 366 (Units Not Provided))	Not Reported
Orencia	S	Unknown	780 Milligram, 1 Every 1 Week	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 365.0 (Units Not Provided)	Not Reported

Remicade	S	Unknown	Unk, Dosage Form Reported As Powder For Solution Intravenous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk, Dosage Form Reported As Powder For Solution Intravenous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligrams, 1 Every 12 Hours	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every 1 Day, Dosage Form Reported As Solution Intravenous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Sulfasalazine	S	Unknown	500 Milligram, Dosage Form Reported As Not Specified	Not Reported
Sulfasalazine	S	Unknown	780 Milligram, 1 Every 1 Weeks (Therapy Duration: 366 (Units Not Provided))	Not Reported
Sulfasalazine	S	Unknown	780 Milligram, 1 Every 1 Weeks (Therapy Duration: 366 (Units Not Provided))	Not Reported
Sulfasalazine	S	Endocervical	Unk, Dosage Form Reported As Not Specified	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Apremilast	S	Unknown	60 Milligram, 2 Every 1 Day	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	Unk	Not Reported

Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram	Not Reported
Cimzia	S	Subcutaneous	Unk, Single-Use Pre-Filled Syringe, Dosage Form Reported As Solution Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Ibuprofen	S	Oral	600 Milligram, Dosage Form Reported As Not Specified	Not Reported
Ibuprofen	S	Oral	Unk	Not Reported
Infliximab	S	Oral	Unk, Dosage Form Reported As Not Specified	Not Reported
Infliximab	S	Oral	Unk	Not Reported
Motrin (Ibuprofen)	S	Oral	600 Milligram, 1 Every 1 Day	Not Reported
Motrin (Ibuprofen)	S	Oral	Unk, 1 Every 1 Day, Dosage Form Reported As Not Specified	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Stelara	S	Subcutaneous	Unk, Dosage Form Reported As Solution Subcutaneous	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Apo Ibuprofen	S	Oral	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Cyclosporine	S	Unknown	Not Specified	Not Reported
Cyclosporine	S	Unknown	Unk	Not Reported
Cyclosporine	C	Unknown	Unk, Dosage Form Reported As Not Specified	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk, Dosage Form Reported As Not Specified	Not Reported

Xeljanz	C	Unknown	Unk	Not Reported
Benadryl	C	Unknown	Unk, Dosage Form Reported As Not Specified	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Colchicine	C	Oral	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk, Dosage Form Reported As Not Specified	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol (Dimenhydrinate)	C	Unknown	Unk, Dosage Form Reported As Not Specified	Not Reported
Gravol (Dimenhydrinate)	C	Unknown	Unk	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Uloric	C	Unknown	80 Milligram, 2 Every 1 Day	Not Reported
Uloric	C	Unknown	80 Milligram	Not Reported
Colchicine	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	16267235	EXPEDITED (15-DAY)		HO	US-BIOGEN-2019BI00729804		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Anger; Cardiac Disorder; Cognitive Disorder; Dyspnoea; Gout; Localised Infection;	Plegridy			S	Subcutaneous			Biogen
	Plegridy			S	Subcutaneous			Biogen
	Plegridy			S	Subcutaneous			Biogen

Malaise; Multiple Sclerosis Relapse; Pain; Seizure; Skin Discolouration; Sleep Disorder; Speech Disorder; Stress; Systemic Lupus Erythematosus	Plegridy	S	Subcutaneous	Biogen
	Hydroxychloroquine	S	Unknown	Not Reported
	Allopurinol	C	Unknown	Not Reported
	Cyanocobalamin	C	Unknown	Not Reported
	Fluticasone	C	Unknown	Not Reported
	Hctz	C	Unknown	Not Reported
	Levetiracetam	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Amlodipine	C	Unknown	Not Reported
	Kcl	C	Unknown	Not Reported
	Ranitidine	C	Unknown	Not Reported
	Temazepam	C	Unknown	Not Reported
	Fluoxetine	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Memantine	C	Unknown	Not Reported
	Diltiazem	C	Unknown	Not Reported
	Fluticasone	C	Unknown	Not Reported
	Warfarin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	16497851	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2019265512		74 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Urinary Tract Infection; Weight Increased	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S		200 Mg, Cyclic (1 On Odd Days, 2 On Even Days)		Not Reported
	Doxazosin Mesylate			C		1 Mg, Daily		Not Reported
	Metoprolol			C		25 Mg, Daily		Not Reported
	Diltiazem			C		120 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	16694396	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-076882		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; Bone Erosion; C-Reactive Protein Increased; Condition Aggravated; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Thrombocytosis	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Apo-Prednisone			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Apo-Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn E			S	Unknown	500 Milligram, Bid		Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown	5 Milligram		Not Reported
	Gabapentin			C	Unknown			Not Reported
	Lovastatin			C	Unknown			Not Reported
	Metoprolol			C	Unknown	50 Milligram		Not Reported
	Naproxen			C	Unknown			Not Reported
	Naproxen Sodium			C	Unknown	1000 Milligram		Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported
	Tramadol Hydrochloride			C	Unknown			Not Reported

	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17275429	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202001000230			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Herpes Zoster; Hypertension; Pneumonia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	0.5 Mg, Bid		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17312883	EXPEDITED (15-DAY)		OT	CA-LUPIN HEALTHCARE (UK) LIMITED-2020-00272		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Loss Of Employment; Off Label Use; Product Use Issue	Cephalexin			S	Unknown	Unk		Lupin
	Losartan Potassium			S	Unknown	Unk		Lupin
	Enalapril Maleate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram Every Week		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Isoniazid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram Every Weeks		Not Reported
	Metoprolol Tartrate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.			S	Unknown	Unk		Not Reported
	Penicillin G [Benzylpenicillin			S	Unknown	Unk		Not Reported

Sodium]					
Plaquenil S	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	50 Milligram, Bid		Not Reported
Leucovorin [Folinic Acid]	C	Unknown	Unk		Not Reported
Coversyl [Perindopril Erbumine]	C	Unknown			Not Reported
Levothyroxine Sodium	C	Unknown	Unk		Not Reported
Colchicine	C	Unknown	Unk		Not Reported
Esomeprazole	C	Unknown	Unk		Not Reported
Ranitidine	C	Unknown	Unk		Not Reported
Atenolol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17312891	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527359			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasopharyngitis; Serum Ferritin Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17312901	EXPEDITED (15-DAY)		OT	CA-LUPIN HEALTHCARE (UK) LIMITED-2020-00278		47 YR	Female	CAN

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

Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Off Label Use; Rash; Therapeutic Product Effect Decreased	Losartan Potassium Tablet	S	Unknown	Unk	Lupin
	Losartan Potassium Tablet	S	Unknown	Unk	Lupin
	Moxifloxacin Hydrochloride	S	Unknown	Unk	Lupin
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Lupin
	Cephalexin	S	Unknown	Unk	Lupin
	Cephalexin	S	Unknown	Unk	Lupin
	Gliclazide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Ciprofloxacin	S	Unknown	Unk	Not Reported
	Clindamycin	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enalapril	S	Unknown	Unk	Not Reported
	Enalapril	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram Every Week	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Lopressor	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram Every Week	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported

	Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.	S	Unknown	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported
	Tecta	S	Unknown	Unk	Not Reported
	Isoniazid	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	50 Milligram, Bid (2 Every 1 Day)	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Atenolol	C	Unknown	Unk	Not Reported
	Colchicine	C	Unknown	Unk	Not Reported
	Coversyl [Perindopril Erbumine]	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Leucovorin [Folinic Acid]	C	Unknown	Unk	Not Reported
	Levothyroxine Sodium	C	Unknown	Unk	Not Reported
	Ranitidine	C	Unknown	Unk	Not Reported
	Venofer	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17313070	EXPEDITED (15-DAY)		DE	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Combivent			S	Unknown			Boehringer Ingelheim
	Alendronate Sodium			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Lasix [Furosemide]			S	Unknown			Not Reported

	Metformin	S	Unknown	Not Reported
	Nitrazadon	S	Unknown	Not Reported
	Omeprazole Magnesium	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Salmeterol Xinafoate	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17313873	EXPEDITED (15-DAY)		OT	CA-ROCHE-2526158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17314401	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528461		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin [Folinic Acid]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17314616	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA013890		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20 Mg		Sanofi
	Leflunomide			S	Unknown	20 Mg		Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Plaquenil			S	Unknown			Sanofi
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous	125.0 Mg, Qw		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Meloxicam	C	Oral	7.5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17314624	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava			S	Unknown	Unk		Sanofi
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17314628	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013892		47 YR	Female	CAN

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

Arthralgia; Burning Sensation; Drug Ineffective; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Leflunomide	S	Unknown	Unk	Sanofi
	Leflunomide	S	Unknown	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Sanofi
	Kevzara	S	Unknown		Sanofi
	Sulfasalazine	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous	40 Mg	Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Unknown	1 G	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, Qd	Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17314645	EXPEDITED (15-DAY)		DS	CA-ROCHE-2531124		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis;	Rituximab			S	Intravenous drip			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

Pain; Physical Disability				otherwise specified)	
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315416	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018196569		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Cetirizine Hydrochloride			S	Unknown	Dosage Form: Unspecified		Glaxosmithkline
	Cetirizine Hydrochloride			S				Glaxosmithkline
	Desoximetasone			S	Oral	Dosage Form: Unspecified		Glaxosmithkline
	Folic Acid			S	Unknown	500 Mg, Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Dosage Form: Unspecified		Not Reported
	Actemra			S	Unknown	Dosage Form: Unspecified		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Dosage Form: Unspecified		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Intracorpus Route		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Dosage Form: Unspecified		Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Dosage Form: Unspecified		Not Reported
	Phthalylsulfathiazole			S	Unknown	Dosage Form: Unspecified		Not Reported

Plaquenil	S	Oral	400 Mg, Once Daily (Qd)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous		Not Reported
Sulfasalazine	S	Oral	1 G Two Every 1 Day		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Cortisone Acetate	S	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315444	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013891			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Qw		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi
	Actemra			S	Unknown			Not Reported
	Enbrel			S		25 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315445	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013887		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Oral	Unk		Sanofi
	Hydroxychloroquine			S	Oral	Unk		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	1.0 G		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	20 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	0.8 Ml, Qd		Not Reported
	Leflunomide			C	Unknown	20 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5.0 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315448	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014219			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pneumonia; Rheumatoid Arthritis; Synovitis	Leflunomide			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Cosentyx			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315449	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013886			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	1 Every 1		Not Reported
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315450	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014603		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Oral	10 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Sanofi
	Celecoxib			S	Oral	200 Mg		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Qow		Not Reported

Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	10 Mg, Qw	Not Reported
Methotrexate	S	Unknown	5 Mg, Qow	Not Reported
Methotrexate	S	Unknown	10 Mg, Qw	Not Reported
Methotrexate	S	Unknown	25 Mg	Not Reported
Methotrexate	S	Unknown	10 Mg	Not Reported
Methotrexate	S	Unknown	7.5 Mg	Not Reported
Methotrexate	S	Unknown	5 Mg	Not Reported
Methotrexate	S	Unknown	25 Mg, Qow	Not Reported
Methotrexate	S	Unknown	10 Mg, Qow	Not Reported
Methotrexate	S	Unknown	7.5 Mg, Qw	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Enbrel	S	Unknown	50 Mg	Not Reported
Enbrel	S	Unknown	25 Mg, Qow	Not Reported
Enbrel	S	Unknown	25 Mg	Not Reported
Enbrel	S	Unknown	50 Mg, Qw	Not Reported
Enbrel	S	Unknown	1 Ml, Qw	Not Reported
Enbrel	S			Not Reported
Humira	S	Unknown	40 Mg	Not Reported
Humira	S	Subcutaneous	40 Mg	Not Reported
Humira	S	Unknown	50 Mg	Not Reported
Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
Orencia	S	Unknown	125 Mg, Qw	Not Reported
Orencia	S	Unknown	12.5 Mg	Not Reported
Orencia	S	Unknown	12.5 Mg, Qow	Not Reported
Acetaminophen;Codeine Phosphate	C		Unk	Not Reported
Altace	C	Unknown	10 Mg	Not Reported
Altace	C	Unknown	5 Mg	Not Reported
Apo-Gabapentin	C	Unknown	300 Mg	Not Reported

Apo-Gabapentin	C	Oral	100 Mg	Not Reported
Apo-Prednisone	C	Oral	15 Mg, Qd	Not Reported
Apo-Prednisone	C	Unknown	5 Mg	Not Reported
Atorvastatin Calcium	C	Oral	40 Mg, Qd	Not Reported
Atorvastatin Calcium	C	Unknown	40 Mg, Qow	Not Reported
Cipralex [Escitalopram]	C	Unknown	10 Mg	Not Reported
Citalopram Hydrobromide	C	Unknown	20 Mg	Not Reported
Conjugated Estrogens	C	Oral	0.625 Mg	Not Reported
Cymbalta	C	Unknown	60 Mg	Not Reported
Cymbalta	C	Unknown	120 Mg, Qd	Not Reported
Cymbalta	C	Unknown	30 Mg, Qid	Not Reported
Escitalopram	C	Unknown	10 Mg	Not Reported
Estrace	C	Unknown	0.5 Mg	Not Reported
Gabapentin	C	Oral	100 Mg	Not Reported
Gabapentin	C	Unknown	300 Mg	Not Reported
Hydrochlorothiazide	C	Subcutaneous	12.5 Mg	Not Reported
Hydromorphone Hydrochloride	C	Oral	3 Mg, Bid	Not Reported
Hydromorphone Hydrochloride	C	Oral	30 Mg, Bid	Not Reported
Mupirocin	C	Topical	Unk	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	20 Mg, Qd	Not Reported
Prednisone	C	Unknown	15 Mg, Qd	Not Reported
Prednisone	C	Oral	5 Mg	Not Reported
Prednisone	C	Oral	5 Mg, Tid	Not Reported
Shark Liver Oil	C	Unknown	Unk	Not Reported
Tapentadol Hydrochloride	C	Unknown	50 Mg	Not Reported
Taro-Mupirocin	C	Topical	Unk	Not Reported
Tramacet	C	Oral	Unk	Not Reported
Tramadol Hydrochloride	C	Oral	50 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315591	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020031847		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Methotrexate Sodium			S	Oral			Pfizer
	Methotrexate Sodium			S				Pfizer
	Enbrel			S				Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Atenolol			C	Oral	50 Mg, 1x/Day		Not Reported
	Hydrochlorothiazide			C	Oral	25 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315735	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527934		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315938	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013861		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17315939	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013872		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Arava			S	Oral			Sanofi
	Sodium Aurothiomalate			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S				Not Reported
	Methotrexate			S		Unk		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Pregabalin			S				Not Reported
	Sulfasalazine			S				Not Reported

Plaquenil	S				Sanofi
Actemra	S		640 Mg, Q4w		Not Reported
Azathioprine	S				Not Reported
Certolizumab Pegol	S		200 Mg, Qow		Not Reported
Certolizumab Pegol	S		200 Mg, Qow		Not Reported
Ciclosporin	S	Oral	Unk		Not Reported
Ciclosporin	S		Unk		Not Reported
Cimzia	S	Subcutaneous	200 Mg, Qw		Not Reported
Enbrel	S		50 Mg		Not Reported
Enbrel	S		50 Ng, Qw		Not Reported
Humira	S	Subcutaneous	40 Mg, Qw		Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Humira	S	Subcutaneous	400 Mg, Qw		Not Reported
Imuran [Azathioprine]	S				Not Reported
Orencia	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Qw		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Unk		Not Reported
Rituxan	S		Solution Intravenous		Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous		Not Reported
Piroxicam	C				Not Reported
Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17316269	EXPEDITED (15-DAY)		OT	CA-ROCHE-2526101			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Finger	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Codeine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rocuronium	S	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17317853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2529157		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetaminophen;Codeine Phosphate			C				Not Reported
	Atacand			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydrodiuril			C				Not Reported
	Neurontin			C	Unknown			Not Reported

	Premarin	C			Not Reported
	Tylenol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318042	EXPEDITED (15-DAY)		OT	CA-ROCHE-2529273		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Advil [Ibuprofen]			C				Not Reported
	Folic Acid			C				Not Reported
	Ketorolac			C				Not Reported
	Methotrexate			C				Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318132	EXPEDITED (15-DAY)		OT	CA-ROCHE-2529977		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Product	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318153	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530659		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318167	EXPEDITED (15-DAY)		DE, HO	US-ASTRAZENECA-2020SE10997		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Esomeprazole			S	Oral			Astrazeneca
	Cyclobenzaprine			S	Oral			Not Reported
	Clindamycin			S	Oral			Not Reported

	Hydroxychloroquine		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318170	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530746		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Operation; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydromorphone Hydrochloride			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318187	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530791			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tiaprofenic Acid	C	Unknown		Not Reported
	Acetylsalicylic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318221	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530837			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318363	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530865			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Enbrel	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318384	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527613		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Warfarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2020	17318402	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528091			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Sedimentation Rate Increased; Synovitis	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2020	16199830	EXPEDITED (15-DAY)		HO, OT	CA-009507513-1904CAN006247		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities;	Fosamax			S	Unknown	70.0 Milligram,Qw (1 Every 1 Week)		Merck
	Fosamax			S	Unknown	70 Milligram, 1 Every 1 Week		Merck
	Fosamax			S	Unknown	Unk		Merck
	Actemra			S	Unknown	360.0 Milligram,Qm (1every 1 Month) (Also Reported As Every 4 Weeks)		Not Reported
	Actemra			S	Unknown	680.0 Milligram, 1 Every 1 Month(Also Reported As Every 4 Weeks)		Not Reported
	Actemra			S	Unknown	680.0 Milligram		Not Reported
	Actemra			S	Unknown	2.68 Milligram, 1 Every 4 Weeks		Not Reported
	Alendronic Acid			S	Unknown	70 Milligram, Qw (1 Every 1 Week)		Not Reported
	Alendronic Acid			S	Unknown	70 Milligram, 1 Every 1 Week		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25.0 Milligram,Biw (2 Every 1 Week)		Not Reported

Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Enbrel	S	Unknown	25 Milligram , (1 Every 2 Weeks)	Not Reported
	Enbrel	S	Unknown	50.0 Milligram, Qw(1 Every 1 Week)	Not Reported
	Enbrel	S	Subcutaneous	25.0 Milligram, Qw (1 Every 1 Week)	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25.0 Milligram	Not Reported
	Enbrel	S	Unknown	50.0 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Unk	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram,Biw (1 Every 2 Weeks)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200.0 Milligram, Qd (1 Every 1 Day)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	20.0 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Unknown	12.0 Milligram, Every 4 Weeks(1every4week)	Not Reported
	Methotrexate	S	Unknown	15.0 Milligram, (1every 4week)	Not Reported
	Methotrexate	S	Unknown	17.5 Milligram, Qw (1 Every 1 Week)	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Qw (1 Every 1 Week)	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qw (1 Every 1 Week)	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Qw (1 Every	Not Reported

			1 Week)	
Methotrexate	S	Subcutaneous	12 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Subcutaneous	15.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Unknown	10 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Unknown	12 Milligram, (1 Every 1 Weeks)	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Unknown	12 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Oral	10 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Unknown	10.0 Milligram	Not Reported
Methotrexate	S	Oral	25 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	12.5 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qm (1 Every	Not Reported

			1 Month)	
Myochrysine	S	Parenteral	50 Milligram, Qm (1 Every 1 Month)	Not Reported
Myochrysine	S	Intramuscular	25.0 Milligram, Qw (1 Every 1 Week)	Not Reported
Myochrysine	S	Intramuscular	50.0 Milligram	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	780.0 Milligram, Qw(1every1week)	Not Reported
Orencia	S	Unknown	760 Milligram, Qw (1 Every 1 Week)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every1 Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	1000.0 Milligram (2 Every 1 Day)	Not Reported
Sulfasalazine	S	Unknown	500.0 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Simponi	S	Unknown	360.0 Milligram, Qm (1 Every 1 Month)	Not Reported
Simponi	S	Subcutaneous	680.0 Milligram, Qm (1 Every 1 Month)	Not Reported
Arava	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10.0 Milligram, Q24h(1every24 Hours) (1	Not Reported

				Every 1 Day)	
	Prednisone	C	Unknown	10 Milligram, Q2h (1 Every 2 Hours)	Not Reported
	Prednisone	C	Unknown	10.0 Milligram	Not Reported
	Prednisone	C	Unknown	20.0 Milligram	Not Reported
	Prednisone	C	Unknown	10.0 Milligram, Qd (1 Every 1 Day)	Not Reported
	Cyclosporine	C	Unknown	150.0 Milligram, Q24h (1every24hours) (1 Every 1 Day)	Not Reported
	Cyclosporine	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	5.0 Milligram, Bid (2 Every 1 Day)	Not Reported
	Xeljanz	C	Oral	5.0 Milligram, Bid (2 Every 1 Day)	Not Reported
	Prednisolone	C	Unknown	Unk	Not Reported
	Prednisolone	C	Unknown	10.0 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2020	14925926	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-009461			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times A Week		Not Reported
	Enbrel			S	Unknown	25 Milligram, Bid		Not Reported
	Enbrel			S	Unknown	25 Milligram,Two Every 1 Week		Not Reported
	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Not Reported

Therapeutic Product Effect Incomplete	Methotrexate Sodium	S	Unknown	15 Milligram, Qwk, 5 Years	Not Reported
	Methotrexate Sodium	S	Unknown	200 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd For 2 Years	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram,1 Every One Day,	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk, For 4 Months	Not Reported
	Humira	S	Unknown	15 Milligram, 1 Every 1 Week	Not Reported
	Humira	S	Subcutaneous	40 Milligram,1 Every Two Week	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk For 8 Months	Not Reported
	Apo-Hydroxyquine	S	Oral	200 Milligram, Bid	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk, For 2 Months	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, 2 Every 1 Week	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram,2 Every One Day	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported

	Leflunomide	S	Unknown	20 Milligram, Qwk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Wellbutrin	C	Oral	Unk	Not Reported
	Sulfasalazine	C	Unknown	1 Gram, Bid	Not Reported
	Bupropion	C	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	12676043	EXPEDITED (15-DAY)		DS, OT	CA-SA-2015SA146389		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis;	Arava			S	Oral	20 Mg, Unk		Sanofi
	Leflunomide			S	Oral	Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Plaquenil			S	Oral	1 Df, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg,Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	1 Df, Qd		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg, Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	4000 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi

Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Pseudoephedrine Hydrochloride	S	Unknown	25 Mg, Unk	Sanofi
	Desoximetasone	S	Oral	Unk	Sanofi
	Desoximetasone	S	Oral	Unk	Sanofi
	Desoximetasone	S	Cutaneous	Unk	Sanofi
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Alendronate Sodium	S		Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Sanofi
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Sanofi
	Hydrocortisone Acetate	S	Unknown	Unk	Sanofi
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G,Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported
	Sulfasalazine	S		1 G, 1 In 12 Hours	Not Reported
	Sulfasalazine	S	Oral	2 Df, Qd	Not Reported
	Paracetamol	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg, Unk	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	25 Mg, Unk	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	10 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Sanofi
	Hydroxychloroquine	S	Oral	Unk	Sanofi
	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	5 Mg	Not Reported

Folic Acid	S	Unknown	25 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk Unk,Prn	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	Unk, Prn	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Golimumab	S	Subcutaneous	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Xeljanz	S		Unk	Not Reported
Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported

	Salazopyrin	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	12913703	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092859		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Off Label Use	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	13516439	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037977			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)		
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Tofacitinib	S	Unknown	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	14823743	EXPEDITED (15-DAY)		OT	CA-ROCHE-2111554		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	Duration 1460 Days		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Anti-D Immunoglobulin			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Lipitor			C	Oral			Not Reported
	Celebrex			C	Oral			Not Reported
	Ibuprofen			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	15399856	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083700			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Orencia			S	Unknown	125 Mg, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	15999216	EXPEDITED (15-DAY)		OT	CA-ROCHE-2268510		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Malignant Melanoma; Product Dose Omission	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Restasis	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	16071582	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05854		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Nail Operation; Onychomadesis; Onychomycosis	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported

Plaquenil	S	Oral	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous, Unknown		Not Reported
Remicade	S	Unknown	Unknown		Not Reported
Xeljanz	S	Unknown			Not Reported
Xeljanz	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Orencia	S				Not Reported
Arava	C	Unknown	Unknown		Not Reported
Arava	C	Oral	Unknown		Not Reported
Orencia	C	Intravenous (not otherwise specified)	Unknown		Not Reported
Orencia	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	16126100	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027156		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Off Label Use; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Voltaren [Diclofenac]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Diclofenac Potassium	S	Unknown	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	16440009	EXPEDITED (15-DAY)		OT	CA-ASSERTIO THERAPEUTICS, INC.-CA-2019DEP000563		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth;	Diclofenac Potassium			S	Unknown	Unk		Assertio Therapeutics
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Mg, Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Mg, Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported

Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound; Wound	Enbrel	S	Subcutaneous	Unk, Weekly	Not Reported
	Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Oral	Unk, Once Ever 24 Hours	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk, Qd	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk, Qd	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Paracetamol	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	Unk, Qd	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported

Reactine /00884302/	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	Unk, Bid	Not Reported
Sulfasalazine	S	Unknown	1000 Mg, Bid	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfathalidine	S	Unknown	1000 Mg, Bid	Not Reported
Sulfathalidine	S	Unknown	500 Mg, Unk	Not Reported
Topicort /00028604/	S	Subcutaneous	Unk	Not Reported
Topicort /00028604/	S	Other	Unk	Not Reported
Xeljanz	S	Unknown	Unk, Bid	Not Reported
Atasol /00020001/	C		Unk	Not Reported
Salazopyrin	C		Unk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	16842013	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27234		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Inflammation; Joint Range Of Motion Decreased; Leg Amputation; Localised	Infliximab			S	Unknown	Unknown		Not Reported
	Infliximab			S	Unknown	Unknown Duration: 579.0		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported

Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Prednisone	S	Unknown	Unknown	Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Acetaminophen	C	Unknown	Unknown	Not Reported
	Acidophilus	C	Unknown	Unknown	Not Reported
	Aspirin	C	Unknown	Unknown	Not Reported
	Calcium	C	Unknown	Unknown	Not Reported
	Crestor	C	Unknown	Unknown	Not Reported
	Deflazacort	C	Unknown		Not Reported
	Dilaudid	C	Unknown	Unknown	Not Reported
	Dilaudid	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	Unknown	Not Reported
	Hydromorph	C	Unknown	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Januvia	C	Unknown	Unknown	Not Reported
	Kenalog	C	Unknown	Unknown	Not Reported
	Kenalog	C	Intra-articular		Not Reported
	Kenalog	C	Unknown	Unknown	Not Reported
	Lidocaine	C	Unknown	Unknown	Not Reported
	Lidocaine	C	Topical	Unknown	Not Reported

Lidocaine	C	Topical		Not Reported
Nitroglycerin	C	Unknown	Unknown	Not Reported
Pantoprazole	C	Unknown	Unknown	Not Reported
Pregabalin	C	Unknown	Unknown	Not Reported
Pregabalin	C	Unknown		Not Reported
Pregabalin	C			Not Reported
Pregabalin	C			Not Reported
Risedronate	C	Unknown		Not Reported
Rosuvastatin Calcium	C	Unknown	Unknown	Not Reported
Rosuvastatin Calcium	C	Unknown		Not Reported
Salbutamol	C	Unknown	Unknown	Not Reported
Metronidazole	C	Unknown	Unknown	Not Reported
Triamcinolone	C	Unknown	Unknown	Not Reported
Triamcinolone	C	Unknown		Not Reported
Xeljanz	C	Unknown	Unknown	Not Reported
Xeljanz	C	Oral		Not Reported
Pantoloc	C	Unknown		Not Reported
Pantoloc	C	Unknown	Unknown	Not Reported
Tylenol	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	16879886	EXPEDITED (15-DAY)		OT	GR-ACCORD-156263		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Exemestane			S	Unknown	Unk		Not Reported
	Ramipril			S	Unknown	Unk		Accord
	Levothyroxine			S	Oral	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported

	Belimumab	S	Unknown	Unk		Not Reported
	Lansoprazole	S	Unknown	Unk		Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported
	Dicoumarol	S	Unknown	Unk		Not Reported
	Levothyroxine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17217695	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-201912003223			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Localised Infection; Peripheral Swelling	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Predonine			C		Unk		Not Reported
	Tacrolimus			C		Unk		Not Reported
	Prograf			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17219722	EXPEDITED (15-DAY)		OT	NVSC2019FR081048		64 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Acneiform	Trametinib			S	Oral	2 Mg, Qd		Novartis
	Trametinib			S	Oral	Unk		Novartis
	Hydroxychloroquine			S	Oral	800 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17298077	EXPEDITED (15-DAY)		OT	FR-ACCORD-168315		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis	Mycophenolic Acid			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported

	Cyclophosphamide/Cyclophosphamide Monohydrate	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Belimumab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17322814	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527604			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17323511	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013997			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Arava			S	Oral	20 Mg		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Prednisone			S	Oral	5 Mg		Not Reported
	Sulfasalazine			S	Unknown	1000 G, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Humira			S	Unknown	20 Mg		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17323862	EXPEDITED (15-DAY)		HO	CA-ROCHE-2523785		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Marijuana			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Minocycline		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Oxycodone Hydrochloride		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Ilaris		C	Subcutaneous	Not Reported
	Lyrica		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17323924	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004134		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk, Qwk, Therapeutic Duartion: 8 Months		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram (Iv)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram (Iv)		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk, Therapeutic Duration: 8 Years		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Meloxicam	C	Oral	7.5 Milligram	Not Reported
	Prednisolone	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17324042	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-003851			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17324252	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202001000338			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Prescribing Error	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Prescribed 1.5 Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17324309	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527620		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Codeine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Acetaminophen;Caffeine	C			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown		Not Reported
	Tylenol No.2	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17324312	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528161		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Bupropion			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17324328	EXPEDITED (15-DAY)		OT	MQ-ALKEM LABORATORIES LIMITED-MQ-ALKEM-2020-00067		53 YR	Female	MTQ

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis; Hyperkeratosis	Mycophenolate Mofetil			S	Unknown	Unk		Alkem

	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported
	Cyclophosphamide	S	Unknown	Unk		Not Reported
	Belimumab	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17324844	EXPEDITED (15-DAY)		HO	CA-ROCHE-2524075		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Parenteral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17324856	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524693		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Diverticulitis; Drug Ineffective; Skin Atrophy; Skin Laceration; Wound	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported
	Perindopril			C	Oral			Not Reported
	Enbrel			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Humira			C	Unknown			Not Reported
	Indapamide			C	Oral			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Pantoloc [Pantoprazole]			C	Oral			Not Reported
	Tylenol			C	Oral			Not Reported
	Rituxan			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17325431	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020032256			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, 1x/Day		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17325515	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020032261			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Joint Swelling; Off Label Use; Product Use Issue; Treatment Failure	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Enbrel			S	Unknown			Pfizer
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326045	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034333			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Furuncle; Pulmonary	Methotrexate Sodium			S	Unknown	Unk		Unknown

Fibrosis; Rheumatoid Arthritis	Sulfasalazine		S	Unknown	500 Mg, 2x/Day	Pfizer
	Xeljanz		S	Oral	5 Mg, 2x/Day	Pfizer
	Xeljanz Xr		S	Oral	11 Mg, 1x/Day	Pfizer
	Humira		S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
	Arava		C	Unknown	20 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326048	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034112			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Unknown
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		300 Mg, 1x/Day		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326055	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020032247		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Injection Site Erythema; Injection Site	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown

Pain; Injection Site Pruritus; Injection Site Reaction; Injection Site Swelling; Injection Site Urticaria; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Sulfasalazine	S		Unk		Pfizer
	Gold	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported
	Benadryl	C	Unknown	Unk		Not Reported
	Naproxen Sodium	C	Unknown	Unk		Not Reported
	Plaquenil S	C	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326065	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034081		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eating Disorder; Eye Disorder; Infection; Intraocular Pressure Increased; Joint Swelling; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Weight Decreased	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown			Unknown
	Sulfasalazine			S	Unknown			Pfizer
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326128	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034091			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S		200 Mg, Weekly		Unknown
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, 1x/Day		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326146	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2020034101			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Unknown
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	10 Mg, 1x/Day		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral	200 Mg, 2x/Day		Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported

	Xeljanz	C	Oral	5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326226	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034073		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Cellulitis; Constipation; Contraindicated Product Administered; Diarrhoea; Eye Disorder; Haemorrhoids; Headache; Herpes Zoster; Mouth Ulceration; Nausea; Pneumonia; Rectal Ulcer; Therapeutic Product Effect Decreased; Ulcer	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Unknown
	Celebrex			S	Oral	200 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	5 Mg, 1x/Day		Pfizer
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, 1x/Day		Not Reported
	Betaloc [Metoprolol Tartrate]			C	Unknown	Unk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Losec [Omeprazole]			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326571	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1008225		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscular Weakness; Myalgia; Peripheral Sensorimotor Neuropathy	Doxycycline			S	Oral	200 Milligram, Qd		Not Reported
	Atorvastatin			S	Oral	40 Milligram, Qd		Not Reported
	Plaquenil /00072602/			S	Oral	3 Dosage Form, Qd		Mylan
	Levofloxacin Hemihydrate			S	Oral	1 Dosage Form, Qd		Mylan
	Metronidazole			S	Oral	1500 Milligram, Qd		Mylan
	Lansoprazole			C	Oral	15 Milligram, Qd		Mylan

Clopidogrel	C	Oral	75 Milligram, Qd		Mylan
Fluconazole	C	Oral	200 Milligram, Qd		Mylan
Ceftriaxone	C	Intravenous (not otherwise specified)	Inconnue		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326638	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020032464			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Eye Ulcer; Keratitis Bacterial; Therapeutic Response Decreased	Methotrexate Sodium			S	Unknown	Unk		Unknown
	Leflunomide			S	Unknown	0.5 Df, Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Every Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Oral	3 G, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17326664	EXPEDITED (15-DAY)		OT	PL-PFIZER INC-2020031610		74 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Dyspnoea; Nausea; Vomiting	Sulfasalazine			S	Oral	2000 Mg, Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17328976	EXPEDITED (15-DAY)		OT	NVSC2020FR013954		66 YR	Male	FRA

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

Eosinophilia; Hepatocellular Injury; Weight Loss Poor	Doxycycline	S	Oral	200 Mg, Qd		Novartis
	Plaquenil	S	Oral	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17330350	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019189		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Hydroxychloroquine Sulfate			S	Unknown	5 Mg		Sanofi
	Leflunomide			S	Oral	10 Mg		Sanofi
	Leflunomide			S		5 Mg		Sanofi
	Certolizumab Pegol			S	Subcutaneous	200 Mg		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Methotrexate			S	Unknown	5 Mg		Not Reported
	Orencia			S	Unknown	750 Mg		Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	50 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jan-2020	17330368	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019246			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypersensitivity Vasculitis; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Rash; Respiratory Tract Infection; Rheumatoid Arthritis; Therapeutic	Plaquenil			S		400 Mg		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Sulfasalazine			S		500 Mg		Not Reported
	Xeljanz			S	Oral	2 Df, Qd (50 Mg)		Not Reported
	Orencia			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Actemra			S				Not Reported

Product Effect Decreased	Atenolol	C			Not Reported
	Celebrex	C			Not Reported
	Colchicine	C			Not Reported
	Coversyl [Perindopril Arginine]	C		Unk	Not Reported
	Hctz	C			Not Reported
	Leucovorin [Folinic Acid]	C	Oral	5 Mg, Qw	Not Reported
	Levothyroxine Sodium	C			Not Reported
	Methotrexate	C	Intramuscular	12.5 Mg, Qw	Not Reported
	Ranitidine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	13676137	EXPEDITED (15-DAY)		OT	CA-ROCHE-1952678		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C				Not Reported
	Elavil [Amitriptyline Hydrochloride]			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

	Premarin	C	Unknown		Not Reported
	Sumatriptan Succinate	C			Not Reported
	Tenormin	C			Not Reported
	Amitriptyline Hydrochloride	C	Unknown		Not Reported
	Tofacitinib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	14702662	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018012999		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Off Label Use; Skin Warm	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Weekly (Qw) Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	15691852	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181138322			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Benadryl			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported

Celebrex	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Pms Azithromycin	S	Unknown		Not Reported
Procytox	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Levofloxacin	S	Unknown		Not Reported
Ezetrol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	15790320	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2018149717		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hypoaesthesia; Immunosuppression; Infection; Influenza; Pyrexia; Rhinorrhoea; Tachycardia; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, Twice Daily		Pfizer
	Xeljanz			S	Oral	5 Mg, Twice Daily		Pfizer
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, Twice Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	16252388	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-039387		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Off Label Use; Respiratory Tract Infection; Rheumatoid Arthritis;	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Sinus Disorder; Sinusitis Noninfective	Enbrel		S	Subcutaneous	50 Microgram, Qwk	Not Reported
	Methotrexate		S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		S	Unknown	Unk	Not Reported
	Celebrex		C	Unknown	Unk	Not Reported
	Ergocalciferol;Retinol;Riboflavin; Thiamine		C	Unknown	Unk	Not Reported
	Esomeprazole Magnesium Trihydrate		C	Unknown	Unk	Not Reported
	Estradiol		C	Unknown	Unk	Not Reported
	Hydroxychloroquine		C	Unknown	Unk	Not Reported
	L-Thyroxine [Levothyroxine]		C	Unknown	Unk	Not Reported
	Tylenol Arthritis Pain		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	16814622	EXPEDITED (15-DAY)		OT	PT-CELLTRION INC.-2019PT024898			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Gastrointestinal Disorder; Interstitial Lung Disease; Product Use In Unapproved Indication; Pulmonary Embolism	Rituximab (Unknown)			S	Unknown	1 G (Twice, 2 Week Apart), Cyclic(9 Cycles)		Not Reported
	Rituximab (Unknown)			S				Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	16830284	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2644831-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective; Off Label Use	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported

	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	16907860	EXPEDITED (15-DAY)		OT	GR-ADVANZ PHARMA-201908000655			Unknown	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Prednisolone			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Azathioprine			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Thyroxine			S	Oral	Unk		Not Reported
	Thyroxine			S	Unknown	Unk		Not Reported
	Lansoprazole			S	Unknown	Unk		Not Reported
	Ramipril			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Not Reported
	Dicumarol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17180364	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027355			Unknown	CAN

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

Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Infliximab Pfizer (Unknown)	S	Intravenous (not otherwise specified)	200 Mg, 1 Every 8 Week (S)	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, 1 Every 15 Day(S)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, 1 Every 15 Day(S)	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, 1 Every 2 Week(S)	Not Reported
	Imuran [Azathioprine Sodium]	S	Unknown	100 Mg, 1 Every 1 Day(S)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Mg, 1 Every 2 Day(S)	Not Reported
	Glyburide	C		750 Mg, 1x/Day	Not Reported
	Infliximab	C		Unk	Not Reported
	Lipitor	C		10 Milligram, 1x/Day	Not Reported
	Metformin	C	Oral	Unk, 2x/Day	Not Reported
	Mycophenolate Mofetil	C	Oral	750 Mg, 2x/Day	Not Reported
	Prednisone	C		5 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17242306	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2019AP026893			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Disability; Dizziness; Gastrointestinal Disorder; Headache; Hypotension; Joint Noise; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Psoriatic Arthropathy; Rheumatoid Arthritis; Sensitivity To Weather Change; Therapeutic Product Effect Decreased;	Leflunomide			S	Oral	10 Mg, Qd		Apotex
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, (Therapy Duration: 365 (Unspecified Unit))		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	10 Mg, Q.Wk.		Not Reported
	Leucovorin /00566701/			S	Oral	5 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk, Qd		Not Reported

Vaginal Haemorrhage; Vomiting; Weight Increased	Naproxen		C	Oral	250 Mg, Unk	Not Reported
	Calcium Citrate W/Magnesium Citrate		C	Unknown	Unk	Not Reported
	Citalopram Hydrobromide		C	Unknown	10 Mg, Unk	Not Reported
	Clobetasol Propionate		C	Topical		Not Reported
	Escitalopram Oxalate		C	Unknown	10 Mg, Unk	Not Reported
	Arava		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17242377	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018036		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Drug Ineffective; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Coversyl /00790702/			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17329962	EXPEDITED (15-DAY)		DE	US-PERRIGO-20US000827		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Pulmonary Oedema; Toxicity To Various Agents	Ibuprofen			S	Oral	Unknown, Single		Perrigo
	Hydroxychloroquine			S	Oral	Unknown, Single		Not Reported
	Naproxen			S	Oral	Unknown, Single		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17330008	EXPEDITED (15-DAY)		HO, OT	DK-MYLANLABS-2020M1009652		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; C-Reactive Protein Increased; Fatigue; Joint Swelling; Off Label Use; Product Use In Unapproved Indication; Weight Decreased	Methotrexate			S	Unknown	20 Milligram, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	250 Milligram, Qd		Not Reported
	Prednisolone			S	Unknown	20 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17330010	EXPEDITED (15-DAY)		DE, HO	GR-MYLANLABS-2020M1009661		57 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Brain Oedema; Condition Aggravated; Confusional State; Encephalitis Japanese B; Meningitis Bacterial; Product Use In Unapproved Indication; Speech Disorder; Treatment Failure	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Unknown	Unk		Mylan
	Rituximab			S				Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S				Mylan
	Prednisolone			S	Unknown	Unk		Mylan
	Prednisolone			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17330516	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019307			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Methotrexate			S	Unknown	15 Mg		Not Reported

	Enbrel			S	Unknown	Unk			Not Reported
	Humira			S	Subcutaneous	Unk			Not Reported
	Orencia			S	Unknown	Unk			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Rituximab			S	Unknown	Unk			Not Reported
	Simponi			C	Subcutaneous	Unk			Not Reported
	Xeljanz			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17332132	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530671		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333374	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Topicort [Desoximetasone]			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333428	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531417		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Humira	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prevacid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333490	EXPEDITED (15-DAY)		HO	CA-ROCHE-2529931		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333511	EXPEDITED (15-DAY)		HO, OT	CN-LUPIN PHARMACEUTICALS INC.-2020-00322		26 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Placenta Accreta; Placenta Praevia; Procedural Haemorrhage	Methylprednisolone			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Alfacalcidol			S	Unknown	Unk		Not Reported
	Alfacalcidol			S	Unknown	Unk		Not Reported
	Calcium & Vitamin D [Calcium;Colecalciferol]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333558	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530420			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333560	EXPEDITED (15-DAY)		OT	CA-ROCHE-2529952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333621	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530460			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

				otherwise specified)	
	Methotrexate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333629	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530416			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333671	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530860		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Infliximab	S	Unknown		Not Reported
	Kineret	S	Subcutaneous	Solution Subcutaneous, 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C			Not Reported
	Desoximetasone	C			Not Reported
	Methotrexate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333695	EXPEDITED (15-DAY)		OT	CA-ROCHE-2526069		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

		otherwise specified)	
Simponi	S	Subcutaneous	Not Reported
Arthrotec	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Imuran [Azathioprine]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17333991	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2530768		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Pain; Peripheral Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral	Solution		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17334133	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004137			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Off Label Use; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
Methotrexate	S	Subcutaneous	25 Milligram		Not Reported
Xeljanz	S	Oral			Not Reported
Kevzara	S	Unknown			Not Reported
Acetaminophen	C	Unknown	650 Milligram, Bid		Not Reported
Atacand	C	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Hydrodiuril	C	Unknown			Not Reported
Kevzara	C	Unknown			Not Reported
Neurontin	C	Unknown	600 Milligram, Tid		Not Reported
Premarin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17334437	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530467		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Infection; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Risedronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17334476	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530491		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17334691	EXPEDITED (15-DAY)		OT	GR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-234388		55 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Sun
	Methylprednisolone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17334999	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC-2019-110099			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Stiffness;	Rheumatrex			S	Unknown	5 Tablets Once Weekly		Dava

Peripheral Swelling	Folic Acid		S	Unknown	1 Mg, Daily	Not Reported
	Hydroxychloroquine		S	Unknown	Unk Unknown, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17335204	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019212		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Eye Disorder; General Physical Health Deterioration; Gluten Sensitivity	Arava			S		Unk		Sanofi
	Celecoxib			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17335211	EXPEDITED (15-DAY)		DS	CA-SA-2020SA019258			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Drug Tolerance	Arava			S	Unknown	Unk		Sanofi
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17335346	NON-EXPEDITED			US-ENDO PHARMACEUTICALS INC-2019-102670			Female	USA

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

Drug Ineffective	Rheumatrex	S	Unknown	Unk Unknown, Unknown	Dava
	Hydroxychloroquine	S	Unknown	Unk Unknown, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17335696	EXPEDITED (15-DAY)		OT	US-CELLTRION INC.-2020US018195			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Alveolar Haemorrhage	Infliximab (Unknown)			S		Unk		Not Reported
	Infliximab (Unknown)			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17335970	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034096			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate Sodium			S		Unk		Unknown
	Orencia			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17335984	EXPEDITED (15-DAY)		DS	CA-PFIZER INC-2020034296			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Drug Tolerance	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported

	Gold		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17335997	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020032434			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective	Methotrexate Sodium			S	Oral	9 Df, Unk		Unknown
	Sulfasalazine			S		Unk		Pfizer
	Apo-Leflunomide			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 2x/Day		Not Reported
	Remicade			S		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Prednisone			C	Oral	5 Mg, 1x/Day		Not Reported
	Prednisone			C		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17336187	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531402		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported

	Myochrysine	S	Intramuscular	Not Reported
	Otezla	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sirukumab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ustekinumab	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17336383	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530627			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Other			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Oral			Not Reported

	Sulfate]				
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17336861	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530870		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Hypersensitivity; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Rheumatoid Arthritis; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported

Diphenhydramine	C	Unknown	Not Reported
Dyclonine Hydrochloride	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Unknown	Not Reported
Loperamide Hydrochloride	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Orphenadrine Citrate	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Sodium Aurothiomalate	C	Intramuscular	Not Reported
Synthroid	C	Unknown	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jan-2020	17336937	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530816			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Desoximetasone	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	11565068	EXPEDITED (15-DAY)		OT	CA-009507513-1509CAN012569			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration;	Fosamax			S	Oral	Unk		Merck
	Fosamax			S		Route: Intra Corpus Cavernosum		Merck
	Fosamax			S	Subcutaneous	Unk		Merck
	Cortisone Acetate			S	Unknown	25 Mg, Unk		Not Reported
	Methotrexate			S	Intra-arterial	25 Mg, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Apo Prednisone	S	Unknown	5 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qw	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Unknown	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg/0.8 Ml, Solution For Injection In Prefilled Syringe	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Oral	400 Mg, 1 Every 1 Day(S)	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, 2 Every 1 Day(S)	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Unknown	Not Reported
	Apo Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Apo Folic Acid	S	Unknown	1, Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Zyrtec	S	Unknown	25 Milligram	Not Reported
	Cortisone	S	Unknown	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Apo Hydroxyquine	S	Unknown	400 Mg, Q24h	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Cetrizine Hydrochloride	S	Unknown	10 Milligram, Unknown	Not Reported
	Cetrizine Hydrochloride	S	Unknown	10 Milligram, Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported

Diclofenac Sodium	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride (+) Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S		Unk, Other	Not Reported
Folic Acid	S	Oral	500 Milligram Per Litre, Unknown	Not Reported
Folic Acid	S		Unk, Unknown	Not Reported
Folic Acid	S	Unknown	5.0 Unk	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk, Unknown	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram, Qd	Not Reported
Prednisone	S	Unknown		Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Stelara	S	Unknown		Not Reported
Golimumab	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Acetaminophen	S	Unknown	Unk, Unknown	Not Reported
Tofacitinib Citrate	S	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Atasol	C	Unknown		Not Reported
Tofacitinib Citrate	C			Not Reported
Ibuprofen	C			Not Reported
Prinivil	C	Unknown		Merck
Cholecalciferol	C	Unknown		Not Reported
Xeljanz	C			Not Reported
Zyrtec	C			Not Reported
Tofacitinib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	12816635	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037708			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Cimzia			S		200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Weekly (Qw) Solution Subcutaneous		Not Reported
	Actemra			S		640 Mg, Ev 4 Weeks		Not Reported
	Actemra			S		640 Milligram, Weekly (Qw)		Not Reported
	Arava			S	Oral	1 Dosage Form, Weekly (Qw)		Not Reported
	Cyclosporine			S	Oral	Unk		Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly (Qw) Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S		300 Milligram, Weekly (Qw)		Not Reported
	Imuran			S		Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Ciclosporin			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Apo-Azathioprine			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, Weekly (Qw)		Not Reported
	Lyrica			S		Unk		Not Reported
	Rituxan			S	Intravenous (not	Solution		Not Reported

			otherwise specified)		
	Orencia	S		Unk	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Mycophenolate Mofetil	S			Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Piroxicam	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	12817973	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016037705		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Bursitis; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Dry Mouth; Facet Joint Syndrome; Headache; Inflammation; Joint Range Of Motion Decreased; Joint Swelling; Lip Dry; Liver Disorder; Lung Disorder; Muscle Spasms; Musculoskeletal Pain; Musculoskeletal Stiffness; Night Sweats; Obesity; Oedema; Oedema Peripheral; Off Label Use; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Peripheral Swelling; Peripheral Venous Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatic Fever; Swelling; Synovitis	Cimzia			S	Subcutaneous	Unk, Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw) (Kit)		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly (Qw)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk, Powder For Solution Intravenous		Not Reported
	Plaquenil			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Xeljanz			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Asa			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Formulation: Solution Subcutaneous		Not Reported
	Calcite D			C		1500 Milligram, Once Daily (Qd)		Not Reported
	Citalopram			C		Unk		Not Reported
	Domperidone			C		Unk		Not Reported
	Folic Acid			C		Unk, 50 Mg		Not Reported
	Gabapentin			C		Unk		Not Reported

	Gliclazide	C	Unk	Not Reported
	Lipitor	C	Unk	Not Reported
	Nifedipine	C	Unk	Not Reported
	Pantoloc	C		Not Reported
	Pantoprazole Sodium	C		Not Reported
	Risedronate	C		Not Reported
	Risedronate Sodium	C	Unk	Not Reported
	Synthroid	C	Unk	Not Reported
	Tylenol Regular	C	650 Mg, 2x/Day (Bid) (Strength :325)	Not Reported
	Acetaminophen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	14307925	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cortisone			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		5 Mg, Unk		Not Reported
	Fosamax			S		Unk Milligram		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S		Unk		Not Reported
	Reactine (Cetirizine Hydrochloride)			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S		500 Mg, Unk	Not Reported
	Apo-Prednisone	S		Unk	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	15714888	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-113697		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diabetes Mellitus; Drug Ineffective; Flushing; Gastrointestinal Disorder; Headache; Hepatic Steatosis; Herpes Zoster; Hypertension; Liver Disorder; Liver Function Test Increased; Nervous System Disorder; Off Label Use; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Gadolinium			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Escitalopram Oxalate			C	Oral	10 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	5 Mg, 1every 1day		Not Reported
	Pantoprazole Magnesium			C	Oral	40 Milligram, Qd		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	15832234	EXPEDITED (15-DAY)		DS	CA-ROCHE-1893094		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chondropathy; Disability; Drug Ineffective; Headache; Malaise; Sarcoidosis; Tooth Extraction; Tooth Fracture; Weight Increased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	15865926	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019002219			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram; Solution Subcutaneous		Not Reported
	Apo-Leflunomide			S		20 Mg, Unk		Not Reported
	Methotrexate			S		20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	17 Milligram, Weekly (Qw)		Not Reported

Decreased	Orencia	S	Intravenous (not otherwise specified)	1000 Milligram, Ev 4 Weeks	Not Reported
	Plaquenil	S		200 Mg, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S		1 G, 2x/Day (Bid)	Not Reported
	Enbrel	S		25 Milligram, 2x/Day (Bid)	Not Reported
	Tofacitinib Citrate	C	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C	Oral	5 Milligram, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	16002106	EXPEDITED (15-DAY)		OT	CA-ROCHE-2269295			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Bacitracin			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Neomycin Sulfate			S	Unknown			Not Reported
	Polymyxin B Sulfate			S	Unknown			Not Reported
	Prednisone			C	Intramuscular			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	16443886	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033243		59 YR	Male	CAN

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

Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Headache; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Tremor; Vitamin D Deficiency	Amlodipine	S	Oral	5 Milligram	Aurobindo
	Amlodipine	S	Oral	5 Milligram, Once A Day	Aurobindo
	Asacol	S	Oral	800 Milligram,3 Every 1 Days	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Every Week	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram,1 Every 2 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	50 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	2.5 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Atacand Plus	C	Oral	Unk, Once A Day	Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Milligram	Not Reported
	Depo-Medrol	C	Intra-articular	120 Milligram	Not Reported
	Depo-Medrol	C	Intramuscular	120 Milligram	Not Reported
	Ferrous Gluconate	C	Oral	300 Milligram	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Omega Allergenic Extracts	C	Unknown	Unk	Not Reported
	Zopiclone	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	500 Milligram	Not Reported

	Vitamin D3		C	Unknown	1000 International Unit, Once A Day	Not Reported
	Pantoprazole Magnesium		C	Unknown	Unk	Not Reported
	Tenofovir Disoproxil Fumarate		C	Unknown	Unk	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	16889211	EXPEDITED (15-DAY)		OT	GR-GLAXOSMITHKLINE-GR2019178532		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Prednisolone			S	Unknown	Unk		Glaxosmithkline
	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Lansoprazole			S	Unknown	Unk		Glaxosmithkline
	Azathioprine			S	Unknown	Unk		Glaxosmithkline
	Ramipril			S	Unknown	Unk		Glaxosmithkline
	Thyroxine			S	Oral	Unk		Glaxosmithkline
	Thyroxine			S	Unknown	Unk		Glaxosmithkline
	Metformin			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Not Reported
	Dicumarol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17004837	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-103665			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance;	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb

Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra	S	Subcutaneous	1 Every 1 Week	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Arava	S	Unknown	20 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	Cyclical	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk,1every1week	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Meloxicam	C	Oral	7.5 Milligram, Prn	Not Reported
	Prednisolone	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram,2every1day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17005829	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-103681		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Methotrexate	S	Oral	25 Milligram, Qd		Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17221372	NON-EXPEDITED		OT	BR-AMGEN-BRASP2019214635		59 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Transient; Conjunctivitis; Product Use Issue	Enbrel			S	Unknown	25 Milligram, 2x/Week		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	50 Mg, Weekly, Once Per Week		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Reuquinol			S	Unknown	400 Mg, 1x/Day		Not Reported
	Methotrexate			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17242162	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026882			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Drug Ineffective; Duodenal Ulcer	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	1000 Mg, Bid		Not Reported
	Zantac			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17242744	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026838		22 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Subcutaneous	162 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	10 Mg, Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17246104	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026844		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Pain; Fibromyalgia; Headache; Injection Site Bruising; Injection Site Pain; Limb Injury; Rheumatoid Arthritis; Road Traffic Accident; Therapeutic Product Effect Decreased	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Enbrel			S	Unknown	Unk, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Arava			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17335940	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-098241			Male	CAN

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

Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Amlodipine	S	Oral	5 Milligram, Once A Day	Aurobindo
	Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, 1 Every 2 Weeks	Not Reported
	Asacol	S	Oral	800 Milligram, 3 Times A Day	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Depo-Medrol	S	Intramuscular	120 Milligram	Not Reported
	Depo-Medrol	S	Intra-articular	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Amlodipine Besilate	C	Unknown	Unk	Not Reported
	Atacand Plus	C	Oral	1 Dosage Form, Once A Day	Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Milligram	Not Reported
	Ferrous Gluconate	C	Oral	300 Milligram	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Omega Allergenic Extracts	C	Unknown	Unk Unk, Once A Day	Not Reported
	Tylenol	C	Oral	500 Milligram	Not Reported
	Vitamin D3	C	Oral	Unk Unk, Once A Day	Not Reported
	Cholecalciferol	C	Unknown	Unk Unk, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17336140	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527623		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported

Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Joint Swelling; Synovitis	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Calcium Carbonate	C	Unknown	Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Sumatriptan Succinate	C		Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17336204	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0537		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Memory Impairment; Rash Erythematous; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Benadryl	C	Unknown	Not Reported
Naproxen Sodium	C	Unknown	Not Reported
Plaquenil S	C	Unknown	Not Reported
Reactine	C	Unknown	Not Reported
Venlafaxine Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17336278	EXPEDITED (15-DAY)		DS	CA-ROCHE-2527578		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Codeine			S	Unknown			Not Reported
	Codeine Phosphate			S	Unknown			Not Reported
	Cosopt			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Levothyroxine	S	Unknown	Not Reported
Levothyroxine Sodium	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Ramipril	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Acetaminophen	C	Unknown	Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Not Reported
Acetaminophen;Caffeine	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Methylprednisolone	C	Unknown	Not Reported
Tylenol With Codeine	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
Caffeine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17336330	EXPEDITED (15-DAY)		HO, OT	CN-LUPIN PHARMACEUTICALS INC.-2020-00439			Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome	Methylprednisolone			S	Transplacental	Unk		Lupin
	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Prednisone			S	Transplacental	Unk		Not Reported
	Alfacalcidol			S	Transplacental	Unk		Not Reported
	Calcium & Vitamin D [Calcium;Colecalciferol]			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17337072	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531552			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17337587	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532604		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

	Methotrexate		S	Unknown	Solution	Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Bupropion		C	Oral		Not Reported
	Sulfasalazine		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17337610	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532608			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17337625	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532612			Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338085	EXPEDITED (15-DAY)		OT	CA-SA-2020SA018845		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Arava			S	Unknown	Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported

Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
Humira	S	Subcutaneous	40 Mg, Qow		Not Reported
Orencia	S	Subcutaneous	750.0 Mg, Qw		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	2000.0 Mg		Not Reported
Etanercept	S	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Qow		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338086	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019339		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Off Label Use; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methyl Salicylate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338087	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019215		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Arava			S	Unknown	20 Mg		Sanofi
	Sulfasalazine			S	Unknown	1 G		Not Reported
	Plaquenil			S	Unknown			Sanofi
	Leflunomide			S	Unknown	20 Mg		Sanofi
	Methotrexate			S	Unknown	20 Mg (Solution)		Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxyquinoline Sulfate			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Rapamune			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tacrolimus			S	Oral	2.0 Mg, 2 Every 1 Days		Not Reported
	Tacrolimus			S	Oral	3 Mg 2 Every 1 Days		Not Reported
	Imuran [Azathioprine]			C	Unknown	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338104	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019084			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Arava			S	Unknown	Unk		Sanofi
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	100 Mg		Not Reported

Humira	S	Subcutaneous	Unk		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Xeljanz	S	Oral	5 Mg, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338108	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019466			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg [2 Every 1 Day]		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338110	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019197			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Pruritus; Synovitis	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid, 2 Every 1 Days		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Ibuprofen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

	Humira	S	Subcutaneous	40 Mg		Not Reported
	Orencia	S	Unknown			Not Reported
	Methotrexate	C	Oral	25 Mg		Not Reported
	Methotrexate	C		25 Mg		Not Reported
	Methotrexate	C	Subcutaneous	25 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338129	EXPEDITED (15-DAY)		OT	FR-GLAXOSMITHKLINE-FR2020011898		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis; Ocular Toxicity	Azathioprine			S	Unknown	Unk		Glaxosmithkline
	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338159	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530847		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported

Naproxen	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338198	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019474			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Arava			S	Unknown			Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Mg		Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown	100 Mg		Not Reported
	Xeljanz			S	Unknown	5 Mg, 2 Every 1 Days		Not Reported
	Hydroxychloroquine			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338202	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019491			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338216	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019534		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Arava			S	Unknown			Sanofi
	Plaquenil			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	15 Mg		Not Reported
	Methylprednisolone			S	Unknown	80 Mg		Not Reported
	Actemra			S				Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338217	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA018854			Female	CAN

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

Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Arava	S	Oral	20 Mg, Qd	Sanofi
	Celecoxib	S	Other	Unk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Gabapentin	S	Oral	100 Mg, Bid	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Qw	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Q3w	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd	Sanofi
	Sulfasalazine	S	Oral	2.5 G, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Mg, Qm	Not Reported
	Enbrel	S	Unknown	50 Mg, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Q3w	Not Reported
	Vitamin B1 Nos	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Aclasta	C	Unknown	Unk	Not Reported
	Actonel	C	Unknown	Unk	Not Reported
	Vitamin C [Ascorbic Acid]	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	Cholecalciferol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Ferrous Fumarate	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Lomotil [Loperamide Hydrochloride]	C	Unknown	Unk	Not Reported
	Loperamide	C	Unknown	Unk	Not Reported
	Nasonex	C	Unknown	Unk	Not Reported

Nortriptyline	C	Unknown	Unk		Not Reported
Pantoprazole	C	Unknown	Unk		Not Reported
Retinol Palmitate	C	Unknown	Unk		Not Reported
Riboflavin	C	Unknown	Unk		Not Reported
Thiamine Hydrochloride	C	Unknown	Unk		Not Reported
Trazodone	C	Unknown	Unk		Not Reported
Tylenol	C	Unknown			Not Reported
Vitamin A [Retinol]	C	Unknown			Not Reported
Vitamin B3	C	Unknown	Unk		Not Reported
Vitamin B1 Nos	C	Unknown	Unk		Not Reported
Vitamin B12 [Cyanocobalamin]	C	Unknown	Unk		Not Reported
Vitamin B6	C	Unknown	Unk		Not Reported
Vitamin C [Ascorbic Acid]	C	Unknown	Unk		Not Reported
Vitamin E Nos	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338465	EXPEDITED (15-DAY)		DS, OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000190			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Skin Exfoliation; Swelling Face	Hydroxychloroquine			S	Oral	200 Milligram, Tid		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338550	EXPEDITED (15-DAY)		OT	CA-ROCHE-2224086		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Arthropathy; Bursitis; Joint Contracture; Joint Effusion; Joint Swelling; Malaise; Ocular Toxicity;	Rituxan			S	Intravenous (not otherwise specified)	Previous Rituximab Infusion: 21/Mar/2019		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Rheumatoid Nodule; Synovial Disorder; Synovitis	Acetaminophen		C	Oral		Not Reported
	Diphenhydramine Hcl		C	Oral		Not Reported
	Hydroxychloroquine		C	Oral	Alternating With 200 Mg Oral Once Daily	Not Reported
	Levothyroxine		C	Unknown		Not Reported
	Methylprednisolone		C	Intravenous (not otherwise specified)		Not Reported
	Prednisone		C			Not Reported
	Spiriva		C	Nasal		Not Reported
	Tylenol		C			Not Reported
	Voltaren [Diclofenac]		C	Unknown	Gel	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338577	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017021010		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 10 Days		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S				Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S				Not Reported
	Xeljanz			S				Not Reported
	Leflunomide			S				Not Reported
	Sarilumab			S				Not Reported
	Tofacitinib			S				Not Reported

Prednisone	C	Oral	5 Mg, Once Daily (Qd)		Not Reported
Rabeprazole Sodium	C	Oral	20 Mg, Unk		Not Reported
Actemra	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338625	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017039111		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Cimzia			S		Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Hydroxychloroquine			S	Subcutaneous	400 Milligram		Not Reported
	Apo-Leflunomide			S		20 Mg, Once Daily (Qd)		Not Reported
	Otezla			S		Unk		Not Reported
	Simponi			S		Solution Subcutaneous		Not Reported
	Enbrel			S		Unk		Not Reported
	Tofacitinib			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338816	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530918		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

Orencia	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338888	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531400		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338921	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020033666		88 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenopia; Eye Pain; Hallucination, Visual; Lacrimation Increased; Vision Blurred; Visual Impairment	Methotrexate Sodium			S		20 Mg, 1x/Day		Pfizer
	Plaquenil			S		2 Df, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338944	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034846		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety;	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer

Blood Pressure Fluctuation; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Osteoarthritis; Palpitations	Methotrexate Sodium	S	Oral	17.5 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	15 Mg, Weekly (1 Every 1 Weeks)	Pfizer
	Sulfasalazine	S	Oral	Unk	Pfizer
	Enbrel	S		50 Mg, Weekly (1 Every 1 Weeks)	Pfizer
	Arava	S	Oral	20 Mg, 1x/Day	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, 1 Every 2 Weeks	Not Reported
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
	Coversyl [Perindopril Erbumine]	C		Unk	Not Reported
	Ergocalciferol	C		Unk	Not Reported
	Leucovorin Calcium	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531424			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	24 Hr		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17338973	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2020034888			Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Methotrexate Sodium		S		Unk	Unknown
	Xeljanz		S		Unk	Pfizer
	Cosentyx		S		Unk	Not Reported
	Hydroxychloroquine		S		Unk	Not Reported
	Leflunomide		S		Unk	Not Reported
	Orencia		S		Unk	Not Reported
	Otezla		S	Oral	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Stelara		S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17339225	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531502			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17339503	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019159		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Ear Pain; Facial Paralysis; Headache; Influenza Like Illness; Insomnia; Nasopharyngitis; Pain In Jaw; Pelvic Prolapse; Post Procedural Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Unknown	Unk		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	12.5 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown			Sanofi
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			S	Oral	5 Mg, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C	Oral			Not Reported
	Desoximetasone			C				Not Reported
	Celebrex			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Fentanyl			C	Unknown	1 Df		Not Reported
	Gabapentin			C	Oral	400 Mg, Bid		Not Reported
	Metformin;Sitagliptin			C	Oral	Unk Unk, Bid		Not Reported
	Perindopril Erbumine			C	Oral	8 Mg, Qd		Not Reported
	Rabeprazole			C	Oral	180 Mg (1 Every 1 Days)		Not Reported
	Ranitidine			C	Oral	150 Mg (1 Every 1 Days)		Not Reported
	Rosuvastatin Calcium			C	Oral	5 Mg (2 Every 1 Days)		Not Reported
	Synthroid			C	Oral	1 Df (1 Every 1 Days)		Not Reported
	Vitamin B 12			C	Oral	Unk Unk, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Zopiclone			C		7.5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17339722	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020034852			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate Sodium			S	Oral	20 Mg, 1x/Day		Pfizer
	Enbrel			S	Subcutaneous			Pfizer
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	200 Mg, 1x/Day		Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Oral	5 Mg, Unk		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17343625	EXPEDITED (15-DAY)		DE, HO	US-JNJFOC-20200134706		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Calcium Increased; Blood Glucose Increased; Blood Potassium Decreased; Blood Sodium Increased; Cardiac Arrest; Haematocrit Decreased; Haemoglobin Decreased; Haemoptysis; Hypotension; Oxygen Saturation Decreased;	Ibuprofen			S	Oral	200 Mg Tablet		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Naproxen			S	Oral	750mg Tablets		Not Reported

Pulmonary Oedema; Toxicity To Various Agents; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17344841	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020038746			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate Sodium			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Xeljanz			S	Oral			Pfizer
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17345715	EXPEDITED (15-DAY)		OT	NVSC2018CA000600		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Cetirizine Dihydrochloride			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	500 Mg		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Dosage Form: Unspecified		Not Reported

Fosamax	S	Unknown	Unk	Not Reported
Fosamax	S	Unknown	Intracorpus Route	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous	Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Cortisone Acetate	S	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jan-2020	17413249	DIRECT	Y	RI			35 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	11579040	EXPEDITED (15-DAY)		OT	CA-UCBSA-2015030469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister;	Cimzia			S	Subcutaneous			Ucb
	Reactine [Cetirizine Hydrochloride]			S		10 Mg		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg		Not Reported

Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Folic Acid	S		5 Mg	Not Reported
	Apo-Folic Acid	S		5mg	Not Reported
	Apo-Hydroxyquine	S		Unk	Not Reported
	Cetirizine	S		10mg	Not Reported
	Prednisone	S		Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk, Weekly (Qw)	Not Reported
	Sulfasalazine	S	Oral	1 G, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S		Unk, Once Daily (Qd)	Not Reported
	Cortisone	S	Oral		Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Sulfathalidine	S		Unk	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported
	Methotrexate	S	Oral	Unk, Once Daily (Qd)	Not Reported

Methotrexate	S		Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Pseudoephedrine Hydrochloride	S		Unk	Not Reported
Diclofenac Sodium	S		Unk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported
Cortisone Acetate	S	Topical	25 Mg	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hy	S		10 Milligram	Not Reported
Apo-Prednisone	S		Unk	Not Reported
Atasol	C			Not Reported
Cortisone Acetate	S			Not Reported
Golimumab	S		Unk	Not Reported
Stelara	S			Not Reported
Leflunomide	S	Oral		Not Reported
Paracetamol	S			Not Reported
Sarilumab	S			Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous		Not Reported
Topicort [Hydrocortisone Acetate]	S			Not Reported
Xeljanz	S		2 Every 1 Days	Not Reported
Salazopyrin	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	12907801	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-089303			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Hypoaesthesia; Off Label Use	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Unk		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	400 Milligram	Not Reported
Apo-Leflunomide	S	Unknown	20 Mg, Qd (1 Every 24 Hours)	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
Pregabalin	C	Oral	50 Mg, Qd (1 Every 24 Hours)	Not Reported
Acetaminophen	C	Unknown	Unk, Prn	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	14310069	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050901		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Cimzia			S	Subcutaneous			Not Reported
	Abatacept			S		Unk		Not Reported
	Adalimumab			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Gold			S		Unk, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Infliximab			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate Sodium			S	Parenteral	25 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium			S	Oral	22.5 Mg, Weekly (Qw)		Not Reported
	Orencia			S		Unk		Not Reported
	Penicillamine			C				Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Tocilizumab	C			Not Reported
	Azathioprine	C		Unk, Once Daily (Qd)	Not Reported
	Ciclosporin	C			Not Reported
	Minocycline	C		Unk	Not Reported
	Prednisolone	C		6 Mg, Once Daily (Qd)	Not Reported
	Prednisone	C		6 Mg, 2x/Day (Bid)	Not Reported
	Actemra	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	14630074	EXPEDITED (15-DAY)		HO, OT	RO-AUROBINDO-AUR-APL-2018-013972		64 YR	Female	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Myocardial Infarction; Angina Pectoris; Coronary Artery Disease; Drug Ineffective; Drug Intolerance; Intentional Dose Omission; Intentional Product Misuse; Rheumatoid Arthritis; Thrombosis In Device; Treatment Noncompliance; Vascular Stent Thrombosis	Clopidogrel			S	Unknown	Unk		Aurobindo
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	30 Milligram (1 Per Week)		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Prednisone			S	Unknown	20 Milligram, Once A Day		Not Reported
	Prednisone			S	Unknown	10 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown	150 Mg, Daily		Not Reported
	Diclofenac			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	14695624	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018012651		70 YR	Female	CAN

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

Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Cimzia	S	Subcutaneous	2 Df, Once Daily (Qd)	Not Reported
	Actemra	S		Unk	Not Reported
	Enbrel	S		50 Mg, Unk	Not Reported
	Methotrexate Sodium	S		Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Plaquenil	S			Not Reported
	Arava	S		Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Hydroxychloroquine	S			Not Reported
	Leflunomide	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Calcium	C		Unk	Not Reported
	Dorzolamide Hcl And Timolol Maleate	C		Unk, 2x/Day (Bid)	Not Reported
	Ergocalciferol	C		Unk, Weekly (Qw)	Not Reported
	Estrogel	C		0.6 %, 3x/Day (Tid)	Not Reported
	Furosemide	C		40 Mg, Once Daily (Qd)	Not Reported
	Potassium Chloride	C		1500 Mg, Once Daily (Qd)	Not Reported
	Valsartan	C		320 Mg, Once Daily (Qd)	Not Reported
	Xalatan	C	Ophthalmic	50 Mg, Once Daily (Qd)	Not Reported
	Tofacitinib Citrate	C			Not Reported
	Morphine	C			Not Reported
	Zingiber Officinale	C		500 Mg, Unk	Not Reported
	Atasol	C		Unk	Not Reported
	Baclofen	C		Unk	Not Reported
	Levaquin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	14911461	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2018020605			Female	CAN

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

Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Off Label Use; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tenosynovitis; Tooth Disorder; Tooth Infection; Weight Decreased	Cimzia	S	Subcutaneous	Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Arava	S		10 Mg, Once Daily (Qd)	Not Reported
	Enbrel	S		Unk	Not Reported
	Hydroxychloroquine	S		400 Mg, Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Ev 4 Weeks	Not Reported
	Prednisone	S		Unk	Not Reported
	Etanercept	S			Not Reported
	Actonel	C		35 Milligram	Not Reported
	Esomeprazole Magnesium Trihydrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	15620559	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2556552-00		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported

Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Triamcinolone Hexacetonide		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	15801002	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2018-1098		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eczema; Herpes Zoster; Hypoaesthesia; Immunosuppression; Infection; Influenza; Mouth Ulceration; Pyrexia; Rheumatoid Arthritis; Rhinorrhoea; Tachycardia; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	16075574	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-012936			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; Colitis; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Amlodipine			S	Oral	5 Milligram, Once A Day		Aurobindo
	Asacol			S	Oral	800 Milligram, 3 Every 1 Day		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, 1 Every 1 Week		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported

Atacand Plus	C	Unknown	Unk		Not Reported
Bisoprolol Fumarate	C	Unknown	Unk		Not Reported
Depo-Medrol	C	Intra-articular	Unk		Not Reported
Omega Allergenic Extracts	C	Intradermal			Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Vitamin D3	C	Unknown	Unk		Not Reported
Ferrous Gluconate	C	Unknown	Unk		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported
Amlodipine Besilate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	16845009	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019397838		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Circumstance Or Information Capable Of Leading To Medication Error; Condition Aggravated; Intervertebral Discitis; Pyrexia; Synovitis; Transaminases Increased	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17002627	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2989507-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cardiac Disorder; Pulmonary Oedema	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17235490	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026896			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Effusion; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17241012	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2019AP026871		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation	Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Abatacept			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Etanercept			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	15 Mg, Q.O.Wk.		Not Reported
	Enbrel			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Infliximab			S	Unknown	200 Mg, Q.M.T.		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Mg, Q.Wk.		Not Reported
	Infliximab			S	Unknown	200 Mg, Q.Wk.		Not Reported

Rate; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S			Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	420 Mg, Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tocilizumab	S			Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17243300	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2020001164		58 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis; Drug Interaction	Ramipril			S	Oral	Unk		Pfizer
	Esomeprazole Sodium			S	Unknown	Unk		Unknown
	Amlodipine Besilate			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Boswellia Serrata;Colecalciferol;Curcuma Longa Rhizome;Glucosamine Sul			S	Unknown	Unk		Not Reported
	Thyroxine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17271509	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-00154		28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Exposure During Pregnancy; Off Label Use; Stillbirth	Methylprednisolone			S	Unknown	Unk		Lupin
	Immunoglobulin I.V			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Plaquenil Sulfate		S	Unknown	Unk	Not Reported
	Azathioprine		S	Unknown	Unk	Not Reported
	Dexamethasone		S	Unknown	Unk	Not Reported
	Etoposide		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17345761	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-026416			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Simponi Aria			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17346862	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202001000446			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Interaction; Dyspnoea; Feeling Abnormal; Head Discomfort; Near Death Experience; Palpitations; Reading Disorder	Hydroxychloroquine			S	Unknown	200 Mg, Qd, Tablet		Concordia
	Prozac			S	Unknown	1 Dosage Form, Qd,		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17346976	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530786			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17347232	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533719		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Coeliac Disease; Drug Ineffective; Fatigue; Grip	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

Strength Decreased; Headache; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis				otherwise specified)	
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Infliximab		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Orencia		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17347258	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533785		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

	Pantoprazole	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17347354	EXPEDITED (15-DAY)		OT	CA-ROCHE-2529944		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Cutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17347506	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020038795			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Dizziness; Dyspnoea; Nausea; Rectal Haemorrhage	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Unknown
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, 1x/Day		Not Reported
	Sulfasalazine			C	Unknown	2 G, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17347548	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020038770			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Folic Acid			C	Oral	5 Mg, Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17347626	EXPEDITED (15-DAY)		HO, OT	US-ROCHE-2535227		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Gastroenteritis Cryptosporidial; Neutropenia; Secondary Immunodeficiency	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17347797	EXPEDITED (15-DAY)		HO, OT	AU-MYLANLABS-2020M1010333		30 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Haemorrhage; Adrenal Insufficiency; Anticoagulation Drug Level Above Therapeutic; Drug Ineffective	Warfarin			S	Unknown	Unk		Not Reported
	Aspirin /00002701/			S	Unknown	Low-Dose		Mylan
	Aspirin /00002701/			S	Unknown	100 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Mylan
	Enoxaparin			S	Unknown	During Attempts To Conceive (Unknown Dose)		Mylan
	Enoxaparin			S	Unknown	After Discontinuation Of Warfarin (Unknown Dose)		Mylan
	Enoxaparin			S	Unknown	120 Milligram		Mylan
	Rituximab			S	Unknown	Two Doses		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17347877	EXPEDITED (15-DAY)		OT	MY-GLAXOSMITHKLINE-MY2020GSK014259		37 YR	Female	MYS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Tinea; Condition	Prednisolone			S		7.5 Mg, Qd		Glaxosmithkline

Aggravated; Cutaneous Vasculitis; Dermatitis Psoriasiform; Drug Intolerance; Erythrodermic Psoriasis; Herpes Zoster; Hypersensitivity Vasculitis; Lupus Nephritis; Musculoskeletal Disorder; Psoriasis; Psoriasis Area Severity Index Increased; Subacute Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus; Systemic Lupus Erythematosus Disease Activity Index Decreased; Therapeutic Product Effect Incomplete; Urinary Tract Infection	Prednisolone	S	30 Mg, Qd	Glaxosmithkline
	Cyclosporine	S	25 Mg, Qd	Glaxosmithkline
	Cyclosporine	S	75 Mg, Qd	Glaxosmithkline
	Azathioprine	S	100 Mg, Qd	Glaxosmithkline
	Acitretin	S	Unk	Glaxosmithkline
	Hydroxychloroquine	S	200 Mg, Qd	Not Reported
	Methotrexate	S	15 Mg, We (Weekly)	Not Reported
	Methotrexate	S	3.5 G	Not Reported
	Ustekinumab	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17348449	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-20K-028-3257305-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Impaired Work Ability; Pyoderma Gangrenosum; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17349316	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020003177		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Joint Swelling;	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported

Off Label Use; Pneumonia; Treatment Failure	Arava	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S		Unk	Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Infliximab	S			Not Reported
	Lidocaine Hydrochloride	S	Subcutaneous		Not Reported
	Orencia	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
	Remicade	S			Not Reported
	Rituximab	S			Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Cephalexin [Cefalexin]	C		500 Milligram, 3x/Day (Tid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17349695	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532036			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350084	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202001000180			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Exposure During Pregnancy; Haemophagocytic Lymphohistiocytosis; Ischaemic Stroke; Respiratory Failure; Stillbirth	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Azathioprine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350323	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020039232			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous			Pfizer
	Actemra			S				Not Reported
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Oral	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Oral	600 Mg, 1x/Day		Not Reported
	Folic Acid			C		1 Df, Weekly		Not Reported
	Prednisone			C				Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral	5 Mg, 1x/Day		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350401	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020003189		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Off Label Use;	Cimzia			S		Solution Subcutaneous		Not Reported
	Actemra			S		50 Milligram, Weekly (Qw)		Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Actemra	S		4.0 Mg/Kg	Not Reported
	Actemra	S		Unk	Not Reported
	Adalimumab	S			Not Reported
	Arava	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine Sulfate	S		200 Milligram, 2x/Day (Bid)	Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	300 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S		200 Milligram, Once Daily (Qd)	Not Reported
	Leflunomide	S		20 Milligram, Once Daily (Qd)	Not Reported
	Lyrica	C			Not Reported
	Methotrexate	C	Oral	Unk, Weekly (Qw)	Not Reported
	Methotrexate	C	Subcutaneous	20 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	C	Subcutaneous	0.8 Milliliter, Weekly (Qw)	Not Reported
	Diclofenac	C			Not Reported
	Celebrex	C			Not Reported
	Orencia	S		1 Dosage Form, Monthly (Qm)	Not Reported
	Orencia	S		750 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S		1.0 Gram	Not Reported
	Rituximab	S		1.0 Gram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1.0 Gram	Not Reported
	Simponi	S	Subcutaneous		Not Reported

Sulfasalazine	C				Not Reported
Tocilizumab	C	Endocervical			Not Reported
Valsartan	C				Not Reported
Xeljanz	C	Oral	5.0 Milligram, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350475	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004615			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Fatigue; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mitral Valve Disease; Pneumonia; Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine Sodium			S	Unknown			Not Reported
	Bactrim			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350794	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1176371		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug	Cephalexin			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Clindamycin Phosphate			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Enalapril			S	Unknown			Actavis

Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Hctz	S	Unknown		Ivax
	Losartan	S	Unknown		Teva
	Methotrexate	S	Subcutaneous	1.4286 Milligram Daily;	Barr
	Metoprolol Tartrate	S	Unknown		Actavis
	Moxifloxacin Hydrochloride	S	Unknown		Teva
	Pantoprazole Magnesium	S	Unknown		Teva
	Arava	S	Unknown		Not Reported
	Biaxin	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Hydralazine Hydrochloride	S	Unknown		Not Reported
	Levaquin	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Pariet	S	Unknown		Not Reported
	Penicillin G 2-Amino-4- Methoxy-6-Methylpyrim	S	Unknown		Not Reported
	Plaquenil S	S	Unknown		Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Gold	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Iron Sucrose	C	Unknown		Not Reported
	Prednisone	C	Unknown	8.5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350874	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005553			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported

	Apo-Leflunomide	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350897	EXPEDITED (15-DAY)		DE	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Atrovent			S	Unknown			Not Reported
	Alendronate Sodium Hydrate			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Albuterol Sulfate And Ipratropium Bromide			S	Unknown			Not Reported
	Lasix [Furosemide Sodium]			S	Unknown			Not Reported
	Lipitor			S	Unknown			Not Reported
	Losec [Omeprazole Magnesium]			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported

	Nitrazadon	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Salmeterol Xinafoate	S	Unknown		Not Reported
	Tylenol	S	Unknown		Not Reported
	Atorvastatin Calcium	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350898	EXPEDITED (15-DAY)		DS	CA-ORION CORPORATION ORION PHARMA-TREX2020-0556			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Drug Tolerance	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350899	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005584			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Pruritus;	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported

Synovitis	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Ibuprofen	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	C	Oral	25 Milligram	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram	Not Reported
	Methotrexate	C	Unknown	25 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17350975	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020003277			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S		567 Milligram, Ev 4 Weeks		Not Reported
	Arava			S		20 Milligram		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S		15 Milligram, Weekly (Qw)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Rituximab			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17351049	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531131		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17351116	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530650		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug	Actemra			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Ciprofloxacin	S	Unknown	Not Reported
	Amoxicillin;Clavulanate Potassium	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tridural	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17351260	EXPEDITED (15-DAY)		HO	CA-ROCHE-2530445		4 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Joint Effusion;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

Joint Injury; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting			otherwise specified)	
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Not Reported
	Triamcinolone Hexacetonide	S	Other	Not Reported
	Vaccinia Immunoglobulins	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17351316	EXPEDITED (15-DAY)		LT	CA-ROCHE-2532218			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Leflunomide			S	Unknown			Not Reported

Leflunomide	S			Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S			Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17351465	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020003182			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia			S	Subcutaneous			Ucb
	Actemra			S				Not Reported
	Arava			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			S	Oral	20 Milligram, Weekly (Qw)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Milligram, 2x/Day (Bid)		Not Reported
	Orencia			S				Not Reported
	Prednisone			C				Not Reported

	Xeljanz	C	Not Reported
	Folic Acid	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17351623	EXPEDITED (15-DAY)		DS, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000067			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Demerol			S	Unknown	Unk		Validus
	Pethidine Hydrochloride			S	Unknown	Unk		Validus
	Pethidine Hydrochloride			S	Unknown	Unk		Validus
	Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk, Qw		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	400 Mg, Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin Estolate			S	Unknown	Unk		Not Reported

Levofloxacin	S	Unknown	Unk		Not Reported
Pregabalin	S	Unknown	Unk		Not Reported
Norfloxacin	S	Unknown	Unk		Not Reported
Plaquenil /00072603/	S	Oral	400 Mg, Qd		Not Reported
Plaquenil /00072603/	S	Oral	Unk		Not Reported
Arthrotec	S	Unknown	Unk		Not Reported
Levofloxacin Hemihydrate	S	Unknown	Unk		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	400 Mg, Unk		Not Reported
Methotrexate Sodium	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17351893	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2020-002237		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Metronidazole			S	Unknown			Not Reported
	Erythro Base			S	Unknown			Bausch And Lomb
	Erythromycin			S	Unknown			Bausch And Lomb
	Erythromycin Estolate			S	Unknown			Not Reported
	Meperidine			S	Unknown			Not Reported
	Methotrexate			S	Oral	Daily		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Apo-Bisoprolol			S	Unknown			Not Reported
	Apo-Norflox			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported

	Celebrex	S	Oral	Not Reported
	Levofloxacin	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Norfloxacin	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported
	Arthrotec	S	Unknown	Not Reported
	Levofloxacin Hemihydrate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Meperidine Hcl	S	Unknown	Not Reported
	Bisoprolol Fumarate	S	Unknown	Not Reported
	Diclofenac Sodium/Misoprostol	S	Unknown	Not Reported
	Celecoxib	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Jan-2020	17352117	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2020044776			Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Premature Baby	Methylprednisolone			S		Unk		Pfizer
	Methylprednisolone			S				Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Alfacalcidol			S		Unk		Not Reported
	Vitamin D2 And Calcium Hydrogen Phosphate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	12331166	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054169		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Headache; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	0.8 Milligram/Kilogram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Unk		Not Reported
	Humira			S	Unknown	40 Milligram Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	300 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	300 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Remicade	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Kineret	S	Subcutaneous	100 Mg, Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Anakinra	S	Subcutaneous	100 Milligram, Unk	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Unk	Not Reported
Methotrexate	S	Oral	20 Milligram	Not Reported
Actonel	S	Oral	35 Milligram, Qwk	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Leflunomide	S	Oral	20 Mg, Qd	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram, Qh	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Risedronate Sodium	S	Unknown	35 Milligram, Qwk	Not Reported
Hydroxychloroquine	S	Unknown	300 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	300 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk Unk, Qd	Not Reported

	Hydroxychloroquine	S	Unknown	300 Milligram	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	300 Milligram, Qh	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk Unk, Qwk	Not Reported
	Risedronate	C	Unknown	35 Milligram, Qwk	Not Reported
	Prednisone	C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	12335415	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016055292		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Impaired Work Ability; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling; Treatment Failure; Vein Disorder	Enbrel			S	Unknown	50 Milligram		Amgen
	Actemra			S	Subcutaneous	162 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

	Folic Acid	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	50 Milligram, Qwk	Not Reported
	Sulfasalazine	S	Unknown	2 Gram	Not Reported
	Fosamax	C	Unknown	Unk	Not Reported
	Ibuprofen	C	Unknown	Unk	Not Reported
	Lisinopril	C	Unknown	Unk	Not Reported
	Vit D3	C	Unknown	Unk	Not Reported
	Alendronate Sodium	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Mtx [Methotrexate]	C		Unk	Not Reported
	Fosavance	C		Unk	Not Reported
	Synthroid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	12572488	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016092115			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Pruritus; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Leflunomide			S	Unknown	Unk Unk, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, 4 Times/Wk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	12901948	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016150079		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; C-Reactive Protein; Diarrhoea; Drug Intolerance; Dyspepsia; Fatigue; Gastrointestinal Disorder; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	20 Milligram		Not Reported
	Sulfasalazine			C	Unknown	1 Gram, 2 Every 1 Day		Not Reported
	Sulfasalazine			C	Unknown	1000 Milligram		Not Reported
	Sulfasalazine			C		500 Milligram		Not Reported
	Trazodone			C		Unk Unk, Qhs		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	14311120	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2017050847		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Wheelchair User	Cimzia			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Leflunomide	S			Not Reported
	Prednisone	C		5 Mg, Once Daily (Qd)	Not Reported
	Methotrexate	C			Not Reported
	Aspirin	C			Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	14311497	EXPEDITED (15-DAY)		DS, HO, OT	CA-UCBSA-2017051050		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomadesis; Onychomycosis	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder And Solvent For Solution For Injection/Infusion		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S		500 Milligram		Not Reported
	Xeljanz			S		5 Milligram, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Oral			Not Reported

	Sulfate]				
	Infliximab	S			Not Reported
	Rituximab	S	Subcutaneous		Not Reported
	Arava	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	15289757	EXPEDITED (15-DAY)		HO, LT, OT	US-APPCO PHARMA LLC-2053873		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conduction Disorder; Hypokalaemia; Mental Status Changes; Overdose; Sinus Tachycardia; Toxicity To Various Agents; Ventricular Arrhythmia; Ventricular Tachycardia	Hydroxychloroquine Sulfate			S	Oral			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	15389922	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018041562		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unknown Dose		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Ev 2 Weeks(Qow)		Not Reported
	Enbrel			S		Unknown Dose		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Hydroxychloroquine			S		Unknown Dose		Not Reported
	Leflunomide			S		Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported
	Orencia			S		750 Milligram, Ev 4 Weeks		Not Reported
	Rituxan			S	Intravenous (not	1 G, Unk		Not Reported

			otherwise specified)		
	Simponi	S	Subcutaneous	50 Milligram, Ev 4 Weeks	Not Reported
	Sulfasalazine	S		Unknown	Not Reported
	Tocilizumab	S		Unknown Dose	Not Reported
	Tofacitinib	S		Unknown Dose	Not Reported
	Tofacitinib Citrate	S		Unknown Dose	Not Reported
	Apo-Leflunomide	S			Not Reported
	Kevzara	S			Not Reported
	Rituximab	S			Not Reported
	Xeljanz	S	Oral	50 Milligram, 2x/Day (Bid)	Not Reported
	Rabeprazole Sodium	C		Unknown	Not Reported
	Methotrexate	C	Oral	20 Milligram, Weekly (Qw)	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Milligram, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	15748179	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2239		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo Leflunomida			S	Unknown			Not Reported

	Actemra	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Magnesium	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	15865362	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019002159		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S		1 Df, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			C		Unk		Not Reported
	Codeine			C		Unk		Not Reported
	Lyrica			C	Oral			Not Reported
	Tylenol			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	15878928	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019002242		48 YR	Female	CAN

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

Arthropathy; Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Hypertension; Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Cimzia	S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)	Not Reported
	Enbrel	S		50 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine Sulfate	S		5 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S		400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S		5 Mg, Unk	Not Reported
	Leflunomide	S	Oral	5 Mg, Unk	Not Reported
	Leflunomide	S	Oral	10 Mg, Unk	Not Reported
	Leflunomide	S		20 Milligram	Not Reported
	Methotrexate	S		5 Mg, Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Orencia	S		750 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Tofacitinib	S	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram	Not Reported
	Apo-Leflunomide	S		20 Milligram	Not Reported
	Apo-Leflunomide	S		5 Milligram	Not Reported
	Gold	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S			Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Arava	C			Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	16108289	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2709179-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea;	Humira			S	Subcutaneous			Not Reported
	Bactrim			S	Oral	160/800 Mg		Not Reported

Drug Hypersensitivity; Drug Intolerance; Drug Intolerance; Eye Disorder; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mammoplasty; Mitral Valve Disease; Off Label Use; Pneumonia; Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Imuran		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Azathioprine Sodium		S	Oral	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	16178863	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2738275-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Warfarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	16858861	EXPEDITED (15-DAY)		OT	GR-TAKEDA-2019TEU011003		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib	Lansoprazole			S	Unknown	Unk		Takeda
	Prednisolone			S	Unknown	Unk		Not Reported

Fracture; Upper Respiratory Tract Infection	Metformin	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Belimumab	S	Unknown	Unk	Not Reported
	Exemestane	S	Unknown	Unk	Not Reported
	Ramipril	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Thyroxin	S	Unknown	Unk	Not Reported
	Thyroxin	S	Oral	Unk	Not Reported
	Dicumarol	C	Unknown	Unk	Not Reported
	Dicumarol	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	16897978	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019430021			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Actemra			S		567 Mg, Monthly		Not Reported
	Arava			S		20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, 2x/Day		Not Reported
	Rituxan			S		Unk		Not Reported
	Celebrex			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	16994165	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019045197		53 YR	Female	CAN

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

Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia	S	Subcutaneous	200 Milligram	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram, Weekly (Qw)	Not Reported
	Certolizumab Pegol	S		200 Milligram, Ev 2 Weeks(Qow)	Not Reported
	Certolizumab Pegol	S		200 Milligram, Ev 2 Weeks(Qow)	Not Reported
	Certolizumab Pegol	S	Subcutaneous	200 Milligram, Weekly (Qw)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	640 Milligram, Monthly (Qm)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	640 Milligram, Ev 4 Weeks	Not Reported
	Actemra	S		640 Milligram, Weekly (Qw)	Not Reported
	Apo-Azathioprine	S			Not Reported
	Apo-Azathioprine	S		Unk	Not Reported
	Arava	S	Oral	Unk, Weekly (Qw)	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Azathioprine	S			Not Reported
	Ciclosporin	S	Oral		Not Reported
	Ciclosporin	S	Oral		Not Reported
	Enbrel	S		50 Milligram, Weekly (Qw)	Not Reported
	Enbrel	S		50 Milligram	Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous	40 Milligram, Weekly (Qw)	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S		400 Milligram, Weekly (Qw)	Not Reported
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Imuran [Azathioprine]	S			Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Milligram, Weekly (Qw)	Not Reported

Infliximab	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Lyrica	S			Not Reported
Methotrexate	S		20 Milligram	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
Mycophenolate Mofetil	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Milligram, 2x/Day (Bid)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Weekly (Qw)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Prednisone	C			Not Reported
Piroxicam	C			Not Reported
Arava	S		20 Milligram	Not Reported
Folic Acid	C			Not Reported
Leflunomide	C			Not Reported
Pregabalin	S			Not Reported
Rituximab	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sodium Aurothiomalate	S			Not Reported
Tofacitinib Citrate	C			Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	16997288	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5145			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17240218	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509529		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Varenicline Tartrate	S	Oral	Not Reported
	Rituxan	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C		Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Oral	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	Not Reported
	Naproxen	C	Unknown	Not Reported
	Naproxen	C	Oral	Not Reported
	Oxycodone Hydrochloride	C		Not Reported
	Rosuvastatin Calcium	C	Oral	Not Reported
	Valtrex	C	Oral	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17240944	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Intolerance; Eye Ulcer; Keratitis Bacterial; Therapeutic Response Decreased	Leflunomide			S	Oral	20.0 Mg, Qd		Apotex
	Leflunomide			S	Unknown	0.5 Df, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Oral	3.0 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17242057	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026849		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arrhythmia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fatigue; Finger Deformity; Gastrointestinal Disorder; Hypersensitivity; Nausea; Pain; Paraesthesia; Swelling; Swollen Joint Count Increased; Urticaria	Leflunomide			S	Oral	20 Mg, Every 1 Day		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Sarilumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352474	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1175997		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Amlodipine Besilate			S	Oral			Teva
	Amlodipine Besilate			S	Oral	5 Milligram Daily;		Teva
	Mesalazine			S	Oral	2400 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Amlodipine Besilate			C	Oral	5 Milligram Daily;		Not Reported
	Atacand Plus			C	Oral			Not Reported
	Bisoprolol Fumarate			C	Oral			Not Reported
	Vitamin D3			C	Unknown	1000 Iu (International Unit) Daily;		Not Reported

	Tylenol	C	Unknown	Not Reported
	Folic Acid	C	Oral	Not Reported
	Ferrous Gluconate	C	Oral	Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Depo-Medrol	C	Intramuscular	Not Reported
	Depo-Medrol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352565	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020003253		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S		300 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)	200 Milligram, 2x/Day (Bid)		Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Methotrexate			S	Subcutaneous	65 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			S	Oral	65 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S		20 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S		25 Milligram, Weekly (Qw)		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352650	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-20K-028-3257168-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand Deformity; Mobility Decreased; Off Label Use; Pain; Product Use Issue; Swelling	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ramipril			C				Not Reported
	Oxycodone Hydrochloride			C				Not Reported
	Acetaminophen			C				Not Reported
	Oxycodone Terephthalate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352739	EXPEDITED (15-DAY)		HO	CA-ROCHE-2529217		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Gabapentin			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	1.0 Dosage Forms		Not Reported

Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Biotin	C		Not Reported
	Cholecalciferolum	C		Not Reported
	Diphenoxylate Hcl	C		Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Ferrous Fumarate	C		Not Reported
	Loperamide	C	Unknown	Not Reported
	Nortriptyline	C	Unknown	Not Reported
	Oxycodone Terephthalate	C		Not Reported
	Pantoprazole Magnesium	C		Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown	Not Reported
	Perphenazine	C		Not Reported
	Prednisone	C		Not Reported
	Pyridoxine	C	Unknown	Not Reported
	Retinol Palmitate	C	Unknown	Not Reported
	Riboflavin	C		Not Reported
	Thiamine Hcl	C		Not Reported
	Thiamine Mononitrate	C		Not Reported
	Trazodone	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Vitamin A [Retinol]	C	Unknown	Not Reported
	Vitamin C [Ascorbic Acid]	C	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Actonel	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352819	EXPEDITED (15-DAY)		HO	CA-ROCHE-2525929		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Ulcer	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352877	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0568		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Osteoarthritis; Palpitations	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Coversyl			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin Calcium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352878	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0574			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Product Use Issue; Rheumatoid	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Oral	Not Reported
	Cimzia	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352879	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0576			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17352966	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3257136-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Eye Disorder;	Humira			S	Subcutaneous			Not Reported

Headache; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Skin Erosion	Methotrexate	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353101	EXPEDITED (15-DAY)		OT	US-ZYDUS-046904		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rebound Effect	Hydroxychloroquine			S	Unknown			Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353157	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530892		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Ramipril			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen;Codeine			C	Unknown			Not Reported

	Caffeine;Dihydrocodeine Bitartrate;Paracetamol	C	Unknown	Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate	C	Ophthalmic	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353165	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531106		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353182	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531411			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Infliximab		S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353208	EXPEDITED (15-DAY)		DE, HO	US-ALVOGEN-2020-ALVOGEN-102618		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Clindamycin			S				Not Reported
	Cyclobenzaprine Hydrochloride			S				Not Reported
	Esomeprazole			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353473	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000447			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Resistance; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Trametinib			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533975		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Responder	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353593	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530486		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Lyrica	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353655	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535837		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530581		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported

Enbrel	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Neoral	S	Oral	Not Reported
Neoral	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17353907	EXPEDITED (15-DAY)		DE	FR-TEVA-2020-FR-1177738		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Interaction; Electrocardiogram Qt Prolonged	Sotalol (Chlorhydrate De)			S	Oral	80 Mg		Teva
	Plaquenil			S	Oral			Not Reported

U.S. FOOD & DRUG ADMINISTRATION

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17355394	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020040977			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Methotrexate Sodium			S	Oral	4 Df, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer
	Leucovorin Calcium			S	Oral	5 Mg, Weekly		Pfizer
	Cosentyx			S	Oral	300 Mg, Monthly		Not Reported
	Diclofenac			S	Oral	Unk, (3 Every 1 Day)		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Golimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, 1x/Day		Not Reported
	Meloxicam			S	Oral	7.5 Mg, 1x/Day		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Oral	1 Df, 1x/Day		Not Reported
	Pantoprazole Magnesium			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Diltiazem Hydrochloride			C	Oral	240 Mg, Unk		Not Reported
	Fluticasone Propionate			C	Respiratory (inhalation)	Unk		Not Reported
	Mar-Pantoprazole			C	Unknown	Unk		Not Reported
	Mometasone Furoate			C	Unknown	Unk		Not Reported
	Premarin			C	Unknown	Unk		Not Reported
	Salbutamol Sulfate			C	Respiratory (inhalation)	Unk		Not Reported
	Tramadol Hydrochloride			C	Oral	Unk Unk, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17355493	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020039223		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Apo-Azathioprine			S	Unknown	100 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Jan-2020	17355826	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-02709		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Wall Haemorrhage; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Haemorrhage; Infection; Influenza Like Illness; Malaise; Nausea; Rheumatoid Arthritis; Urinary Tract Infection	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Prednisone	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous	Not Reported
	Plaquenil	C	Oral		Not Reported
	Sulfasalazine	C	Unknown	Unknown	Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	15854681	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633525-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rabeprazole Sodium			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	16851800	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2937832-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rapamune			S	Unknown			Not Reported
	Tacrolimus			S	Oral			Not Reported
	Tacrolimus			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxyquinoline Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Imuran			C	Unknown			Not Reported
	Azathioprine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358261	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3256489-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Inflammation; Musculoskeletal Stiffness;	Humira			S	Subcutaneous	10 Months		Not Reported
	Plaquenil			S	Oral			Not Reported

Retinopathy	Enbrel	S	Subcutaneous	Not Reported
	Xeljanz	C	Oral	Not Reported
	Methotrexate	C	Oral	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358339	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531525		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358340	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531538		76 YR	Female	CAN

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

Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Actemra		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358348	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531587			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358349	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530929			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Actemra			S	Unknown			Not Reported

Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358352	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532032		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Atenolol			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358358	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532601			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Solution	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358367	EXPEDITED (15-DAY)		HO	CA-ROCHE-2530347		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Gabapentin			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Celecoxib			S	Oral			Not Reported
	Celecoxib			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fentanyl Matrix			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Nortriptyline			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Nasonex	C	Unknown	Not Reported
	Aclasta	C	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported
	Ascorbic Acid	C		Not Reported
	Biotin	C		Not Reported
	Calcium	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Esomeprazole	C		Not Reported
	Fentanyl	C	Unknown	Not Reported
	Ferrous Gluconate	C	Unknown	Not Reported
	Fish Oil	C	Unknown	Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		Not Reported
	Loperamide	C		Not Reported
	Esomeprazole	C		Not Reported
	Nortriptyline	C	Unknown	Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]	C		Not Reported
	Omega 3-6-9 [Fish Oil]	C	Unknown	Not Reported
	Oxycodone Terephthalate	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Pyridoxine	C		Not Reported
	Sodium	C		Not Reported
	Thiamine Hcl	C		Not Reported
	Trazodone	C		Not Reported
	Tylenol	C		Not Reported
	Vitamin A [Retinol]	C		Not Reported

	Vitamin B3	C	Unknown		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358674	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358677	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533827			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Infliximab		S	Unknown	Not Reported
	Kineret		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Desoximetasone		C		Not Reported
	Methotrexate		C		Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358682	EXPEDITED (15-DAY)		OT	CA-ROCHE-2534194			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17358684	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533757			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia;	Actemra			S	Intratumor			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Pyelonephritis; Rash; Urosepsis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2020	17376781	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531725			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	11310374	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015073223		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthritis; Blood Creatinine Decreased; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Discharge; Eye Disorder;	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Acetaminophen			S	Oral	65 Milligram		Not Reported
	Acetaminophen			S	Unknown	Unk		Not Reported

Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Vision Blurred; White Blood Cell Count Decreased	Acetaminophen	S	Oral	65 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	520 Milligram, Q4wk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	520 Milligram	Not Reported
	Dilaudid	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, 4 Times/Wk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Prednisone	S	Unknown	7.5 Milligram	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Apo Hydromorphone	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Apo-Acetaminophen	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydromorphone	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qd	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	15.5 Unk	Not Reported

Hydromorphone Hydrochloride	S	Unknown	Unk	Not Reported
Calcium Folinate	S	Unknown	5 Milligram	Not Reported
Humira	C	Subcutaneous	Unk	Not Reported
Humira	C	Unknown	Unk	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	C	Unknown	Unk	Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	C	Oral	50 Milligram	Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Unk	Not Reported
Fosavance	C		Unk Unk, Qwk	Not Reported
Hydrocortisone	C	Intravenous (not otherwise specified)	250 Milligram	Not Reported
Hydrocortisone	C	Unknown	Unk	Not Reported
Hyzaar	C		12.5 Milligram, Qd	Not Reported
Hyzaar	C	Unknown	Unk	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Methylprednisolone	C	Unknown	Unk	Not Reported
Alendronate Sodium;Colecalciferol	C		Unk Unk, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	11490879	NON-EXPEDITED		HO, LT, OT	CA-AMGEN-CANSP2015093585		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone	Enbrel			S	Subcutaneous	12.5 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Amgen
	Enbrel			S	Subcutaneous	12.5 Milligram, Qd		Amgen

Density Decreased; Bone Density Increased; C-Reactive Protein	Enbrel	S	Unknown	25 Milligram, Qwk	Amgen
Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting;	Enbrel	S	Unknown	1.5 Milligram, Qwk	Amgen
	Enbrel	S	Subcutaneous	25 Milligram	Amgen
	Enbrel	S	Unknown	12.5 Milligram, Qwk	Amgen
	Enbrel	S	Unknown	4 Dosage Form, Qwk	Amgen
	Enbrel	S	Subcutaneous	12.5 Milligram, 4 Times/Wk	Amgen
	Enbrel	S	Subcutaneous	25 Milligram, Bid	Amgen
	Enbrel	S	Unknown	25 Milligram	Amgen
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Cyclical	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Q2wk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Immune Globulin Intravenous (Human)	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk	Not Reported
	Infliximab	S	Unknown	5 Milligram	Not Reported

Wheelchair User	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram Cyclical	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram	Not Reported
	Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Adalimumab	S			Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter 12 Every 2 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Milligram, Qmo	Not Reported
	Orencia	S		250 Milligram, Qmo	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Milligram, Qmo	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported

Prednisone	S	Oral	5 Milligram, Bid	Not Reported
Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	2 Dosage Form, Qd	Not Reported
Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
Anakinra	S	Unknown	Unk, Qd	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Subcutaneous	1 Dosage Form, Qd	Not Reported
Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, Qd	Not Reported
Triamcinolone	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
Triamcinolone	S	Unknown	Unk	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	250 Milligram, Qmo	Not Reported
Abatacept	S			Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
Immunoglobulin (Immunoglobulin Human Normal)	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S			Not Reported
Methotrexate Sodium	S	Unknown	Unk, Qwk	Not Reported
Methotrexate Sodium	S			Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, Bid	Not Reported

Apo-Prednisone	S	Oral	5 Milligram, 2 Times/Wk	Not Reported
Apo Triamcinolone Aq	S	Intra-articular	Unk	Not Reported
Apo Triamcinolone Aq	S			Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	S	Oral	5 Milligram, Qd	Not Reported
Triamcinolone Acetonide	S			Not Reported
Triamcinolone Acetonide	S			Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	1 Dosage Form, Qd	Not Reported
Gammagard	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Triamcinolone Hexacetonide	C	Unknown	Unk	Not Reported
Triamcinolone Hexacetonide	C	Intra-articular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	12635667	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016101720		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk (Solution)		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

Responder; Tuberculin Test Positive			otherwise specified)		
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo Celecoxib	S	Oral	200 Milligram, Bid	Not Reported
	Celecoxib	S	Oral	200 Milligram, Bid	Not Reported
	Toradol	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	7-10 Milligram, Unk	Not Reported
	Tramadol	C	Unknown	100 Milligram, As Necessary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	14321179	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017110785		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	16120605	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019044829			Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel		S	Unknown	Unk Unk, Qwk	Amgen
	Actemra		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk Unk, Bid	Not Reported
	Methotrexate		S	Unknown	Unk Unk, Qwk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Sulfasalazine		C	Unknown	Unk Unk, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2020	17358981	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020015573		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	12302836	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016051354		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event; Off Label Use; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	12579837	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016355316			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Pruritus; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, 4 Times/Wk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	13908882	NON-EXPEDITED		HO, LT, OT	CA-AMGEN-CANSP2017127671		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement;	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

Terminal State; Thrombosis	Remicade	S	otherwise specified)		
			Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S			Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	14421683	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018006742		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease;	Enbrel			S	Unknown	Unk		Amgen

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Methotrexate	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Bid	Not Reported
	Bactrim	S	Unknown		Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	14868417	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2018061435		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Arthralgia; Arthropathy; Cholecystectomy; Contraindicated Product Administered; Dermatitis; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gallbladder Disorder; Gastric Disorder; Groin Pain; Hip Surgery; Joint Swelling; Miliaria; Off Label Use; Pancreatitis; Photosensitivity Reaction; Pruritus Allergic; Rheumatoid Arthritis; Sleep Disorder; Stomatitis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	11:1 Milligram, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Morphine			S	Unknown	Unk		Not Reported
	Morphine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Orencia	S	Unknown	Unk		Not Reported
Cyclosporine	S	Unknown	Unk		Not Reported
Celecoxib	S	Unknown	200 Milligram, Q12h		Not Reported
Dilaudid	S	Unknown	Unk		Not Reported
Citalopram	C		10 Milligram, Qd		Not Reported
Pantoloc	C		40 Milligram, Bid		Not Reported
Pantoloc	C				Not Reported
Prednisone	C	Unknown	10 Milligram, Qd		Not Reported
Celebrex	C	Unknown	200 Milligram, Bid		Not Reported
Lorazepam	C	Unknown	1 Milligram, Qhs (At Bedtime)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16055007	EXPEDITED (15-DAY)		OT	CA-ROCHE-2277556		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16084291	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1022664		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort;	Diclofenac Sodium			S	Unknown			Actavis

Adverse Drug Reaction; Adverse Event; Alopecia; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pain; Pemphigus; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Systemic Lupus Erythematosus; Wound	Leflunomide	S	Oral		Barr
	Methotrexate	S	Oral	2 Gram Daily;	Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Oral		Barr
	Prednisone	S	Unknown		Actavis
	Prednisone	S			Actavis
	Paracetamol	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S			Not Reported
	Arava	S	Oral		Not Reported
	Arava	S			Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Cimzia Single-Use Prefilled Syringe	S			Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Subcutaneous		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Apo-Hydroxychloroquine	S	Unknown		Not Reported
	Apo-Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported

Apo-Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Subcutaneous		Not Reported
Phthalylsulfathiazole	S	Subcutaneous		Not Reported
Phthalylsulfathiazole	S			Not Reported
Plaquenil/00072603/	S	Oral		Not Reported
Plaquenil/00072603/	S			Not Reported
Reactine//Cetirizine Hydrochloride	S	Unknown		Not Reported
Reactine//Cetirizine Hydrochloride	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S			Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Oral	500 Milligram Daily;	Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Prednisone	S			Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Sarilumab	S	Unknown		Not Reported
Topicort	S	Subcutaneous		Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16129066	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-027216		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Orencia			S	Unknown			Bristol Myers Squibb
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported
	Asacol			S	Oral	800 Milligram, Tid		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Mesalazine			S	Oral	800 Milligram, Tid		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Amlodipine Besilate			C	Oral	5 Milligram, Qd		Not Reported
	Atacand Plus			C	Oral	Unk, Qd		Not Reported
	Bisoprolol Fumarate			C	Oral	2.5 Milligram		Not Reported
	Depo-Medrol			C	Intra-articular	120 Milligram		Not Reported
	Depo-Medrol			C	Intramuscular	120 Milligram		Not Reported
	Ferrous Gluconate			C	Oral	300 Milligram		Not Reported
	Folic Acid			C	Oral	5 Milligram		Not Reported
	Omega Allergenic Extracts			C	Unknown			Not Reported
	Tylenol			C	Unknown	500 Milligram		Not Reported
	Vitamin D3			C	Unknown	1000 International Unit, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16201898	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019058114			Female	CAN

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

Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	Unk	Amgen
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Naproxen	C		500 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16443920	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033823		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling;	Metformin			S	Unknown	500 Milligram, Two Times A Day		Aurobindo
	Desoximetasone			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Therapeutic Product Effect Decreased	Sulfasalazine	S	Unknown	Unk	Not Reported
	Altace	C	Unknown	5 Milligram, Once A Day	Not Reported
	Asa	C	Unknown	81 Milligram, Once A Day	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	1 Dosage Form, 6 Every 1 Week	Not Reported
	Methotrexate	C	Oral	15 Milligram, Once A Day	Not Reported
	Rosuvastatin Calcium	C	Unknown	20 Milligram, Once A Day	Not Reported
	Vitamin D	C	Unknown	Unk	Not Reported
	Omega 3	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16521599	EXPEDITED (15-DAY)		OT	CA-ROCHE-2346118		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	16829773	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1109222		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Bisoprolol			S	Unknown			Duramed
	Bisoprolol			S	Unknown			Duramed
	Celecoxib			S	Oral	200 Milligram Daily;		Teva
	Diclofenac W/Misoprostol			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Levofloxacin			S	Unknown			Teva
	Methotrexate			S				Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Norfloxacin			S	Unknown			Not Reported
	Bisoprolol Fumurate			S	Unknown			Duramed
	Levofloxacin Hemihydrate			S	Unknown			Teva
	Methotrexate Sodium			S	Unknown			Barr
	Apo-Bisoprolol			S	Unknown			Not Reported
	Apo-Norflox			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Ceclor			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Demerol			S	Unknown			Not Reported
	Erythro Base			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			S	Unknown			Not Reported
	Meperidine			S	Unknown			Not Reported

Meperidine Hcl	S	Unknown			Not Reported
Plaquenil	S	Oral	400 Milligram Daily;		Not Reported
Plaquenil	S	Oral			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Erythromycin	S	Unknown			Not Reported
Metronidazole	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17261096	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP005141			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200.0 Mg, Unk		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Doxycycline Hyclate			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Q.M.T.		Not Reported
	Prednisone			C	Unknown	10.0 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	25.0 Mg, Unk		Not Reported
	Xeljanz			C	Unknown	50 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17270951	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP005142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Doxycycline			S	Unknown	50 Mg, Unknown		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	10.0 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Unknown	5.0 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359168	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005580			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Bifidobacterium Bifidum			C	Unknown	Unk		Not Reported
	Loperamide			C	Oral	Unk		Not Reported

	Pantoprazole	C	Unknown	Unk, Tid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359226	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533869		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Other			Not Reported
	Triamcinolone Hexacetonide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359267	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533849		57 YR	Male	CAN

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

Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Desoximetasone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359279	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533864			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gammagard			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Kineret		S	otherwise specified) Subcutaneous	100 Mg Per Syringe Single Use, Preservative- Pre Filled Syringes	Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Naproxen		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		S	Oral		Not Reported
	Prednisone		S	Oral		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Triamcinolone		S	Subcutaneous		Not Reported
	Triamcinolone Acetonide		S	Unknown		Not Reported
	Triamcinolone Acetonide		S			Not Reported
	Triamcinolone Acetonide		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359286	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533836			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immunoglobulin Human Normal			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported

In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Immunoglobulin Human Normal		S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)		Not Reported
	Infliximab		S	Unknown		Not Reported
	Kineret		S	Subcutaneous	Solution Subcutaneous, 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Naproxen		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		S	Oral		Not Reported
	Prednisone		S	Oral		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Triamcinolone		S	Other		Not Reported
	Triamcinolone Hexacetonide		S	Intra-articular	Suspension Intraarticular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359348	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532707			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Hydroxychloroquine	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359365	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532680			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

	Triamcinolone	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359389	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532679			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gp2013			S	Intravenous (not otherwise specified)	Therapy Duration: 1.0 Months		Not Reported
	Gp2013			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 610.0 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 4.0 Years		Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Months		Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 5.0 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359475	EXPEDITED (15-DAY)		HO	CA-ROCHE-2531147		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Occlusive dressing technique			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Actonel			C				Not Reported
	Vitamin C [Ascorbic Acid]			C				Not Reported
	Biotin			C				Not Reported
	D-Alpha Tocopherol			C				Not Reported
	Ergocalciferol			C				Not Reported
	Esomeprazole			C				Not Reported
	Ferrous Fumarate			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]			C				Not Reported
	Loperamide			C				Not Reported
	Nasonex			C				Not Reported
	Nicotinamide			C				Not Reported
	Nortriptyline			C				Not Reported
	Pantoprazole			C				Not Reported

	Prednisone	C	Not Reported
	Pyridoxine	C	Not Reported
	Retinol Palmitate	C	Not Reported
	Riboflavin	C	Not Reported
	Sodium Ascorbate	C	Not Reported
	Thiamine	C	Not Reported
	Thiamine Hydrochloride	C	Not Reported
	Trazodone	C	Not Reported
	Tylenol	C	Not Reported
	Vitamin A [Retinol]	C	Not Reported
	Vitamin B12 [Cyanocobalamin]	C	Not Reported
	Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359490	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201904-001246			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Meningitis Aseptic	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd (Daily Administration)		Concordia
	Micardis			C		Unk		Not Reported
	Thyradin S			C		Unk		Not Reported
	Baktar			C		Unk		Not Reported
	Baktar			C				Not Reported
	Takepron			C		Unk		Not Reported
	Takepron			C				Not Reported
	Onealfa			C		Unk		Not Reported
	Onealfa			C				Not Reported
	Bonalon			C		Unk		Not Reported
	Bonalon			C				Not Reported
	Persantin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359581	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2543863-00			Female	CAN

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

Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Pruritus; Synovitis	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Ibuprofen	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359641	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531537		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Fatigue; Hand Deformity; Headache; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359679	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-006501			Female	CAN

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

Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia	S	Intravenous (not otherwise specified)	Bristol Myers Squibb
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359682	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0585			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

	Arava	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359689	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0594			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359691	EXPEDITED (15-DAY)		HO	CA-ROCHE-2531148		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actonel			C				Not Reported
	Aclasta			C				Not Reported
	Esomeprazole			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Genteal [Carmellose Sodium;Hypromellose]			C				Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]			C				Not Reported
	Nasonex			C				Not Reported
	Esomeprazole			C				Not Reported
	Nortriptyline			C				Not Reported
	Prednisone			C				Not Reported
	Trazodone			C				Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359693	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000512			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypothyroidism	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359849	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532669			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359891	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532661			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17359996	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533770		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported

Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Enbrel	S	Unknown	Not Reported
	Fentanyl	S	Unknown	Not Reported
	Gabapentin	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Calcium	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Ferrous Gluconate	C	Unknown	Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	Not Reported
	Nasonex	C	Unknown	Not Reported
	Nortriptyline Hydrochloride	C	Oral	Not Reported
	Omega-3 Fatty Acids	C	Unknown	Not Reported
	Oxycodone Terephthalate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Trazodone Hydrochloride	C	Oral	Not Reported
	Tylenol	C	Oral	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C		Not Reported
	Aclasta	C		Not Reported
	Actonel	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360047	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533775		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Sunconjunctival			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360147	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-092402		59 YR	Male	CAN

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

Arthralgia; C-Reactive Protein Decreased; Colitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Vitamin D Deficiency	Amlodipine	S	Oral	5 Milligram	Aurobindo
	Methotrexate	S	Subcutaneous	25 Milligram, One Every 2 Weeks	Not Reported
	Asacol	S	Oral	800 Milligram, 3 Times A Day	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Amlodipine Besilate	C	Unknown	Unk	Not Reported
	Atacand Plus	C	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Omega Allergenic Extracts	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360197	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535489			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Cimzia Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360276	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533780			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Acetaminophen And Codeine	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360307	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533782		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533783			Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Actemra		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Gold		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360441	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533784		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Unknown	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Triamcinolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360448	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533790			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360506	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0610			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360817	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531843		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Imuran [Azathioprine]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17360983	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531687		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling;	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported

Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methylprednisolone		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Unknown	Not Reported
	Naproxen		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17361304	EXPEDITED (15-DAY)		DE	US-GLENMARK PHARMACEUTICALS-2020GMK045822		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide	Naproxen			S	Oral	Unk		Glenmark
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Ibuprofen			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362077	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020043730			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown			Pfizer
	Actemra			S	Unknown			Not Reported

Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day		Not Reported
Leflunomide	S	Unknown	10 Mg, 1x/Day		Not Reported
Lyrica	C	Unknown			Not Reported
Naproxen	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362094	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005520			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362158	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532892			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported

Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone Acetonide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362159	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532688		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Other	Not Reported
	Triamcinolone Hexacetonide	C	Intra-articular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362187	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020041070		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Enbrel			S	Subcutaneous	50 Mg, Monthly		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362841	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1178156			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash	Ciprofloxacin			S	Unknown			Not Reported
	Clindamycin			S	Unknown			Actavis
	Enalapril			S	Unknown			Actavis
	Hydrochlorothiazide			S	Unknown			Ivax
	Losartan			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Moxifloxacin Hydrochloride			S	Unknown			Teva
	Pantoprazole Magnesium			S	Unknown			Teva

Codeine	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Biaxin	S	Unknown	Not Reported
Celebrex	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Isoniazid	S	Unknown	Not Reported
Keflex	S	Unknown	Not Reported
Levaquin	S	Unknown	Not Reported
Lopresor	S	Unknown	Not Reported
Pariet	S	Unknown	Not Reported
Penicillin	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Cipro	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Gold	C	Unknown	Not Reported
Hydroxyquinoline Sulfate	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Saccharated Iron Oxide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362927	EXPEDITED (15-DAY)		OT	CA-SA-2020SA003084			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Maculopathy; Retinopathy; Treatment Failure	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Myochrysine			S		Unk		Not Reported
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported

	Methotrexate	S	Oral	20 Mg, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Q4w	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Qw	Not Reported
	Enbrel	C	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	C	Subcutaneous	40 Mg, Qow	Not Reported
	Prednisone	C		1 Mg, Qd (Prn)	Not Reported
	Prednisone	C		5 Qd (Prn)	Not Reported
	Prednisone	C		4 Mg, Qd (Prn)	Not Reported
	Prednisone	C		3 Mg, Qd (Prn)	Not Reported
	Prednisone	C		2 Mg, Qd (Prn)	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Codeine	C			Not Reported
	Morphine	C			Not Reported
	Demerol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17362930	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024485		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Hydroxychloroquine Sulfate			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Tylenol			C				Not Reported
	Prednisone			C		5 Mg, Qd		Not Reported
	Prednisolone Acetate			C		5 Mg, Qd		Not Reported
	Leflunomide			C				Not Reported
	Desoximetasone			C		5 Mg, Qd		Not Reported

	Cyclobenzaprine	C	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363122	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023780			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Sarilumab			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1.0 G		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Tofacitinib			S		Unk		Not Reported
	Xeljanz			S		Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg		Not Reported
	Methotrexate			C		Unk		Not Reported
	Rabeprazole Sodium			C	Oral	20 Mg, Qd		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363123	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023722			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Plaquenil			S		400 Mg		Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Minocycline Hydrochloride			S				Not Reported
	Sulfasalazine			S				Not Reported
	Azathioprine			S		100 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S		5 Mg, Qd (2 Every 1 Days)		Not Reported
	Hydroxychloroquine			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363226	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Sublingual			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

				otherwise specified)	
	Methotrexate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363232	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533732			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363250	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533735		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Positive; Nausea; Obesity; Product Use In Unapproved Indication; Product Use Issue; Septic Shock; Vomiting	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363261	EXPEDITED (15-DAY)		HO	CA-ROCHE-2532637			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Red Blood Cell	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Subcutaneous	Therapy Duration:- 404.0 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration:- 5.0 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363315	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533753		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported
	Lasix [Furosemide]			C				Not Reported
	Naprosyn [Naproxen]			C				Not Reported
	Oxycontin			C	Unknown	Tablet (Extendedrelease)		Not Reported
	Oxyneo			C	Unknown	Tablet (Extendedrelease)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363386	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		63 YR	Female	CAN

BMS-2020-005934

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363416	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532632			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363643	EXPEDITED (15-DAY)		DS	CA-SA-2020SA024097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Infection; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Plaquenil			S				Sanofi
	Prednisone			S		10 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1500 Mg, Bid		Not Reported
	Levothyroxine Sodium			S				Not Reported
	Leflunomide			S				Sanofi
	Orencia			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S				Not Reported
	Etanercept			S		1 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363905	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005936			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Feb-2020	17363959	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005958			Female	CAN

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

Bone Erosion; Diverticulitis; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Orencia	S	Unknown		Bristol Myers Squibb
	Actemra	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	1500 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	10677800	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2014100610		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Aclasta			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Sulfasalazine			S	Oral	2 Gram, Qd		Not Reported
	Tramacet			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	17.5 Mg - 25mg Every		Not Reported

Arthritis; Sleep Disorder; Spinal Operation; Spinal Stenosis; Treatment Failure				Week	
	Methotrexate	S	Unknown	Unk, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	1 Dosage Form, Qd	Not Reported
	Tramadol/Acetaminophen	S	Oral	Unk	Not Reported
	Metformin	C	Unknown	5 Milligram, Qd	Not Reported
	Metformin	C	Unknown	500 Milligram, Bid	Not Reported
	Lorazepam	C		1 Milligram, Once Nightly	Not Reported
	Lorazepam	C		1 Milligram, Qd	Not Reported
	Nortriptyline Hydrochloride	C	Unknown	20 Milligram, Qd	Not Reported
	Vagifem	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	0.625 Milligram	Not Reported
	Vitamin D	C		Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Tylenol Arthritis Pain	C		Unk	Not Reported
	Actonel	C		35 Milligram, Qwk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Milligram, Qmo	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Unk, Qmo	Not Reported
	Methylprednisolone Acetate	C			Not Reported
	Depomedrol	C	Intramuscular	40 Mg, Qmo	Not Reported
	Depomedrol	C	Subcutaneous	Unk Unk, Qmo	Not Reported
	Depomedrol	C			Not Reported
	Lyrica	C	Oral	150 Milligram, Bid	Not Reported
	Nortriptyline	C	Unknown	Unk (Tablet And Capsule)	Not Reported
	Nortriptyline	C			Not Reported
	Risedronate Sodium	C	Unknown	35 Milligram, Qwk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	11231394	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015064666		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk (Powder For Suspension)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	11515749	EXPEDITED (15-DAY)		HO, LT, OT	CA-PFIZER INC-2015293060		365 DAY	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive	Enbrel			S	Subcutaneous	12.5 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	25 Mg, Every Two Week		Pfizer
	Enbrel			S	Subcutaneous	25 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	25 Milligram		Pfizer
	Enbrel			S	Subcutaneous	12.5 Mg, 1x/Day		Pfizer

Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous	25 Mg, Weekly	Pfizer
	Enbrel	S	Subcutaneous	12.5 Mg, 4times/Wk	Pfizer
	Enbrel	S	Unknown	25 Milligram, Qwk	Pfizer
	Enbrel	S	Unknown	1.5 Milligram, Qwk	Pfizer
	Enbrel	S	Unknown	12.5 Milligram, Qwk	Pfizer
	Enbrel	S	Unknown	4 Dosage Form, Qwk	Pfizer
	Enbrel	S	Subcutaneous	25 Milligram, Bid	Pfizer
	Enbrel	S	Unknown	Unk	Pfizer
	Infliximab Hospira	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly (1 Every 1 Week)	Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)	5 Mg/Dose, Unk	Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)	3 Mg/Kg, Cyclic (Once Every 6 Weeks)	Not Reported
	Infliximab Hospira	S	Unknown	Unk	Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)	3 Mg, Weekly (1 Every 1 Week(S))	Not Reported
	Infliximab Hospira	S	Unknown	3 Mg, Weekly	Not Reported
	Infliximab Hospira	S		5 Mg, Unk	Not Reported
	Methotrexate Sodium	S		15 Mg/M2, Weekly	Unknown
	Methotrexate Sodium	S	Subcutaneous	15 Mg/M2, Weekly	Unknown
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Unknown
	Methotrexate Sodium	S	Unknown	Unk	Unknown
	Methotrexate Sodium	S		15 Mg, 2x/Week	Unknown
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk	Unknown
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter 12 Every 2 Weeks	Unknown
	Methotrexate Sodium	S		Unk	Unknown
	Methotrexate Sodium	S	Unknown	1 Dosage Form, Qwk	Unknown
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter,	Unknown

			Qwk	
Sulfasalazine	S	Oral	250 Mg, Qd(1 Every 24 Hour(S))	Pfizer
Sulfasalazine	S	Unknown	250 Mg, 1x/Day	Pfizer
Sulfasalazine	S	Oral	1 Dosage Form, Qd	Pfizer
Triamcinolone	S	Unknown	Unk	Unknown
Triamcinolone	S		Unk	Unknown
Triamcinolone	S		Unk	Unknown
Infliximab	S	Unknown	3 Mg, Weekly	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	3 Unk	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unk	Pfizer
Triamcinolone Acetonide	S	Unknown	Unk	Pfizer
Triamcinolone Acetonide	S	Oral	5 Milligram, Qd	Pfizer
Triamcinolone Acetonide	S			Pfizer
Hydroxychloroquine	S	Oral	5 Mg/Kg, 1x/Day (Daily)(1 Every 24 Hour(S))	Not Reported
Hydroxychloroquine	S	Oral	5 Mg/Kg, Daily	Not Reported
Hydroxychloroquine	S	Oral	Unk Unk, Qd (5.0)	Not Reported
Hydroxychloroquine	S	Oral	1 Dosage Form, Qd	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S			Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	1.3 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Week	Not Reported
Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported

Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	2 Dosage Form, Qd	Not Reported
Prednisone	S	Oral	3 Milligram	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Immunoglobulin Human Normal	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immunoglobulin Human Normal	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Anakinra	S	Subcutaneous	50 Mg, 1x/Day (Daily) (1 Every 24 Hour(S))	Not Reported
Anakinra	S	Unknown	50 Mg, Weekly	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Unknown	50 Mg, 1x/Day Qd	Not Reported
Anakinra	S	Subcutaneous	1 Dosage Form, Qd	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	250 Mg, Monthly	Not Reported
Abatacept	S		250 Mg, Qmo	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Cyclic (2 Every 1 Week(S))	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unk	Not Reported
Immunoglobulins Nos	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immunoglobulins Nos	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Monthly (1 Every 1 Month (S))	Not Reported
Orencia	S	Unknown	250 Mg, Monthly Inhalation	Not Reported
Orencia	S	Intravenous (not	250 Mg, Unk	Not Reported

		otherwise specified)		
Orencia	S	Unknown	250 Mg, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Weekly (1 Every 1 Week)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, 2x/Week	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported
Actemra	S		280 Mg, Cyclical	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, 1x/Day Qd	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Q2wk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Kineret	S	Subcutaneous	50 Mg, 1 Every 1 Day	Not Reported
Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Naproxen	S			Not Reported
Apo-Prednisone	S	Oral	3 Mg, 2x/Day(2 Every 1 Day(S))	Not Reported
Apo-Prednisone	S	Oral	5 Mg, 2x/Day(2 Every 1 Day(S))	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, 2 Times/Wk	Not Reported
Apo Triamcinolone Aq	S	Unknown	Unk	Not Reported
Apo Triamcinolone Aq	S	Intra-articular	Unk	Not Reported

	Gammagard	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Gammagard	S			Not Reported
	Apo-Hydroxyquine	S	Oral	5 Mg, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Mg, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Mg/Kg, 1x/Day	Not Reported
	Gamastan	S	Intramuscular	70 G, Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unk	Not Reported
	Triamcinolone Hexacetonide	C	Intra-articular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	12304669	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015013797		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	10 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milliliter, Bid		Not Reported
	Xeljanz			S	Oral	10 Milliliter, Bid		Not Reported
	Xeljanz			S	Oral	Unk, Bid		Not Reported
	Xeljanz			S	Oral	10 Milliliter		Not Reported
	Xeljanz			S	Oral	5 Milliliter		Not Reported
	Celebrex			S	Oral	Unk		Not Reported

Celebrex	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Vioxx	S	Oral	Unk	Not Reported
Vioxx	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	20 Milligram	Not Reported
Methotrexate	S	Unknown	200 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	C		Unk	Not Reported
Wellbutrin	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	12343875	NON-EXPEDITED		OT	CA-AMGEN-CANSL2016055527		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Drug	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	Unk		Not Reported

Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Arava		S	Subcutaneous	Unk	Not Reported
	Gold		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Methotrexate		S	Subcutaneous	Unk	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Unknown	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Apo Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate		S	Unknown	Unk	Not Reported
	Rituximab		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	12695500	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016245898		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Impaired Work Ability;	Enbrel			S	Unknown	50 Mg, Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Sulfasalazine			S		Unk		Pfizer

Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling; Treatment Failure; Vein Disorder	Actemra	S	Subcutaneous	162 Milligram	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Qwk	Not Reported
	Folic Acid	S		Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	50 Milligram, Qwk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Fosamax	C		Unk	Not Reported
	Ibuprofen	C	Unknown	Unk	Not Reported
	Lisinopril	C	Unknown	Unk	Not Reported
	Vit D3	C	Unknown	Unk	Not Reported
	Alendronate Sodium	C	Unknown	Unk	Not Reported
	Mtx [Methotrexate]	C		Unk	Not Reported
	Fosavance	C		Unk	Not Reported
	Synthroid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	13299527	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016375688		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Lupus-	Enbrel			S	Unknown	Unk		Pfizer
	Celecoxib			S	Oral	200 Mg, Bid		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Tuberculin Test Positive	Orencia	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk (Solution)	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo Celecoxib	S	Oral	200 Mg, Bid	Not Reported
	Toradol	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	7-10 Mg, Unk	Not Reported
	Tramadol	C	Unknown	100 Mg, As Necessary	Not Reported
	Prednisone	C		7-10 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	13330098	EXPEDITED (15-DAY)		OT	CA-ROCHE-1693450			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Peripheral Swelling; Rash; Tendon Disorder; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	13917842	EXPEDITED (15-DAY)		HO, LT, OT	CA-PFIZER INC-2017371881		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram		Pfizer
	Apo Sulfasalazine			S		Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S			Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	14328853	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017297972		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	14639970	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		61 YR	Female	CAN

PHARMA-TREX2018-0752

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Overdose; Product Use Issue; Rheumatoid Arthritis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	14817954	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2018054977		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Amgen
	Enbrel			S	Unknown	25 Milligram, Qwk		Amgen
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	25 Milligram, Unk		Not Reported
	Orencia			S	Subcutaneous	250 Milligram, Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Unk	Not Reported
Salazopyrin	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
Gold	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	20 Milligram, Bid	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Unk	Not Reported
Hydroxychloroquine	S	Unknown	300 Milligram, Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
Prednisone	C		40 Milligram, Unk	Not Reported
Prednisone	C		250 Milligram, Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Unk	Not Reported

Xeljanz	C	Unknown	Unk		Not Reported
Bifidobacterium Bifidum	C	Unknown	Unk		Not Reported
Celebrex	C	Unknown	Unk		Not Reported
Arava	C	Oral	10 Milligram, Unk		Not Reported
Loperamide	C	Unknown	Unk		Not Reported
Wellbutrin	C	Unknown	Unk		Not Reported
Pantoprazole	C	Unknown	Unk		Not Reported
Simponi	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15278631	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018110461			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15348973	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175923		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15348992	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175991		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Desoximetasone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15412513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186027		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Restasis			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15436734	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190086		56 YR	Male	CAN

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

C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Stomatitis; Urticaria	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Marijuana	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15638561	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA-978039		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Drug Ineffective; Fungal Infection; Off Label Use; Osteomyelitis; Systemic Infection; Systemic Mycosis	Voriconazole			S	Unknown			Teva
	Voriconazole			S	Oral			Teva
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Unknown	40 Milligram Daily;		Actavis
	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Amphotericin B			S	Unknown			Not Reported
	Amphotericin B			S	Intravenous (not otherwise specified)	200 Milligram Daily;		Not Reported

	Amphotericin B	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15683328	EXPEDITED (15-DAY)		HO, LT, OT	CA-CELLTRION INC.-2018CA024265			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness;	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly (1 Every 1 Week)		Not Reported
	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	5 Mg/Dose, Unk;		Not Reported
	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	3 Mg/Kg, Cyclic (Once Every 6 Weeks)		Not Reported
	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	3 Mg, Weekly (1 Every 1 Week(S))		Not Reported
	Infliximab Pfizer (Unknown)			S	Unknown	3 Mg, Weekly		Not Reported
	Infliximab Pfizer (Unknown)			S	Unknown	5 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Weekly		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, 2x/Week		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, 1x/Day		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, 4times/Wk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	1.5 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	4 Dosage Form, Qwk		Not Reported

Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous	25 Milligram, Bid	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg/M2, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg/M2, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S		15 Mg, 2x/Week	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter, Q2wk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter 12 Every 2 Weeks	Not Reported
	Methotrexate Sodium	S		Unk	Not Reported
	Methotrexate Sodium	S	Unknown	1 Dosage Form, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram/Sq. Meter	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd(1 Every 24 Hour(S))	Not Reported
	Sulfasalazine	S	Unknown	250 Mg, 1x/Day	Not Reported
	Sulfasalazine	S	Oral	1 Dosage Form, Qd	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	3 Mg, Weekly,Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Unk	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unk	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unk	Not Reported
	Triamcinolone Acetonide	S	Oral	5 Milligram, Qd	Not Reported
	Triamcinolone Acetonide	S		Unk	Not Reported
	Hydroxychloroquine	S	Oral	5 Mg/Kg, 1x/Day (Daily)(1	Not Reported

			Every 24 Hour(S))	
Hydroxychloroquine	S	Oral	5 Mg/Kg,	Not Reported
Hydroxychloroquine	S	Oral	Unk Unk, Qd (5.0)	Not Reported
Hydroxychloroquine	S	Oral	1 Dosage Form, Qd	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	1.3 Mg, 2x/Day	Not Reported
Prednisone	S	Oral	5 Mg, 2x/Week	Not Reported
Prednisone	S	Oral	3 Mg, 2x/Day	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	2 Dosage Form, Qd	Not Reported
Prednisone	S	Oral	3 Milligram	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Anakinra	S	Subcutaneous	50 Mg, 1x/Day (Daily) (1 Every 24 Hour(S)),	Not Reported
Anakinra	S	Unknown	50 Mg, Weekly	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Unknown	50 Mg, 1x/Day Qd	Not Reported
Anakinra	S	Subcutaneous	1 Dosage Form, Qd	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	250 Mg, Monthly	Not Reported

Abatacept	S		250 Mg, Qmo	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Cyclic (2 Every 1 Week(S)),	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Unk	Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unk	Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Monthly (1 Every 1 Month (S)	Not Reported
Orencia	S		250 Mg, Monthly Inhalation	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Unk	Not Reported
Orencia	S	Unknown	250 Mg, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Weekly (1 Every 1 Week)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, 2x/Week	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported
Actemra	S	Unknown	280 Mg, Cyclical	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, 1x/Day Qd	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qwk	Not Reported

Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Q2wk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Kineret	S	Subcutaneous	50 Mg, 1 Every 1 Day	Not Reported
Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Naproxen	S		Unk	Not Reported
Apo-Prednisone	S	Oral	3 Mg, 2x/Day(2 Every 1 Day(S))	Not Reported
Apo-Prednisone	S	Oral	5 Mg, 2x/Day(2 Every 1 Day(S))	Not Reported
Apo-Prednisone	S	Oral	5 Milligram, 2 Times/Wk,	Not Reported
Apo Triamcinolone Aq	S	Unknown	Unk	Not Reported
Apo Triamcinolone Aq	S	Intra-articular	Unk	Not Reported
Gammagard	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
Gammagard	S		Unk	Not Reported
Apo-Hydroxyquine	S	Oral	5 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Mg, 1x/Day	Not Reported
Gamastan	S	Intramuscular	70 G, Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Triamcinolone Hexacetonide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15710539	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018303849		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Enbrel			S	Unknown	50 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer

Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate Sodium		S	Unknown	Unk	Pfizer
	Sulfasalazine		S	Unknown	300 Milligram, Qd	Pfizer
	Sulfasalazine		S	Unknown	500 Milligram	Pfizer
	Arava		S	Unknown	20 Mg, Qd	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Simponi		S	Unknown	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Apo Leflunomida		S	Unknown	20 Milligram	Not Reported
	Apo Leflunomida		S	Unknown	Unk	Not Reported
	Actemra		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	400 Milligram, Qd	Not Reported
	Calcium		C	Unknown	Unk	Not Reported
	Magnesium		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported
	Mtx		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15719053	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016245381		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Headache; Hypertension; Infection; Intentional Product Use	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Unknown
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day, (Bid)		Pfizer
	Actemra			S	Subcutaneous	Unk		Not Reported

Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S		0.8 Mg/Kg, Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Kineret	S	Subcutaneous	100 Mg, Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	20 Mg, 1x/Day, (Qd)	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclic, (Q2wk)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Plaquenil	S	Unknown	300 Mg, Daily ((200mg:1 And A Half Pill), Qd)	Not Reported
	Plaquenil	S	Oral	300 Mg, 1x/Day, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Cyclic: On Day 0 And Day 15	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S		1 G, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported

Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S		Unk	Not Reported
Gold	S		Unk	Not Reported
Anakinra	S	Subcutaneous	100 Mg, Unk	Not Reported
Anakinra	S		Unk	Not Reported
Apo-Hydroxyquine	S	Oral	20 Mg, Unk, (Every Hour)	Not Reported
Apo-Hydroxyquine	S		20 Mg, Daily, (Every Hour)	Not Reported
Actonel	S	Oral	35 Mg, Weekly, Qwk	Not Reported
Leflunomide	S	Oral	20 Mg, 1x/Day, Qd	Not Reported
Apo-Leflunomide	S	Oral	20 Mg, Cyclic, Qh	Not Reported
Apo-Leflunomide	S		20 Mg, Daily (Qd (1 Every 24 Hour(S))	Not Reported
Apo-Leflunomide	S		Unk, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S		Unk, 1x/Day, Once Every 24 Hours	Not Reported
Risedronate	S		35 Mg, Weekly	Not Reported
Hydroxychloroquine	S		300 Mg, 1x/Day, Qd	Not Reported
Hydroxychloroquine	S		300 Mg, 1x/Day, Qd	Not Reported
Hydroxychloroquine	S		Unk	Not Reported
Hydroxychloroquine	S		Unk Unk, Qd	Not Reported
Hydroxychloroquine	S		300 Mg, Unk	Not Reported
Risedronate	C		35 Mg, Weekly, Qwk	Not Reported
Hydroxychloroquine Sulfate	C		300 Mg, Cyclic, Qh	Not Reported
Hydroxychloroquine Sulfate	C		Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	200 Mg, 2x/Day, Bid	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk, Weekly, Qwk	Not Reported
Prednisone	C		10 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15867790	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019002236			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Reactine (Cetirizine Hydrochloride)			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Cortisone Acetate			S		Unk		Not Reported
	Plaquenil			S				Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Diclofenac Sodium			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	16092462	EXPEDITED (15-DAY)		OT	PHHY2019CA057177			Female	CAN

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

Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Cosentyx	S	Unknown		Novartis
	Methotrexate	S	Unknown	Unk Unk, Unknown	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk Unk, Unknown	Not Reported
	Enbrel	S	Unknown	Unk Unk, Unknown	Not Reported
	Humira	S	Subcutaneous	Unk Unk, Unknown	Not Reported
	Otezla	S	Oral	Unk Unk, Unknown	Not Reported
	Plaquenil	S	Unknown	Unk Unk, Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Unknown	Not Reported
	Simponi	S	Subcutaneous	Unk Unk, Unknown	Not Reported
	Stelara	S	Subcutaneous	Unk Unk, Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unk Unk, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	16454389	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019134150			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Enbrel			S	Unknown	Unk Unk, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk Unk, Qwk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Bid		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	16831220	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3552		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Circumstance Or Information Capable Of Leading To Medication Error; Condition Aggravated; Intervertebral Discitis; Pyrexia; Synovitis; Transaminases Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Unknown	Strength: 500 Mg		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	16891747	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2019-28949		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Adalimumab			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Humira	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Naproxen	S			Not Reported
	Prednisone	S	Oral		Not Reported

Prednisone	S	Oral			Not Reported
Prednisone	S	Oral			Not Reported
Prednisone	S	Unknown	Unknown		Not Reported
Sulfasalazine	S	Oral			Not Reported
Sulfasalazine	S				Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)			Not Reported
Triamcinolone	S	Unknown			Not Reported
Triamcinolone	S	Subcutaneous			Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown		Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown		Not Reported
Triamcinolone Acetonide	S	Unknown	Unknown		Not Reported
Triamcinolone Acetonide	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Orencia	S	Unknown			Not Reported
Orencia	S	Unknown			Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unknown		Not Reported
Naproxen Sodium	S	Unknown	Unknown		Not Reported
Folic Acid	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	16912193	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-201910001021			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Neoplasm Of Conjunctiva	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Unk, Qd		Concordia
	Mizoribine			C	Unknown	Unk		Not Reported
	Tacrolimus Monohydrate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17030148	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201911001623			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cardiac Disorder; Pulmonary Oedema	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	40 Mg, 1 In 2 Wk (40mg/0.4ml(40 Milligram, Solution For Injection In Pre-Filled Pen)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17273061	EXPEDITED (15-DAY)		DE, HO, OT	US-PFIZER INC-2020016994		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suspected Suicide	Clindamycin Hcl			S	Oral	Unk		Pfizer
	Esomeprazole Magnesium			S	Oral	Unk		Unknown
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Cyclobenzaprine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17274911	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005784		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown			Apotex
	Abatacept			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	4 Df, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Not Reported

Rituximab	S	Unknown		Not Reported
Simponi	S	Subcutaneous	50 Mg, Q.M.T.	Not Reported
Tylenol /00020001/	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Tylenol Arthritis Pain	C	Unknown	Unk, Prn	Not Reported
Prednisone	C	Unknown	24 Mg, Qd	Not Reported
Prednisone	C	Unknown	23 Mg, Qd	Not Reported
Prednisone	C	Unknown	25 Mg, Qd	Not Reported
Prednisone	C	Unknown	10 Mg, Qd	Not Reported
Celebrex	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17339418	EXPEDITED (15-DAY)		HO	CA-ROCHE-2530858		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab		S	Intravenous (not otherwise specified)		Not Reported
	Kineret		S	Subcutaneous	Solution Subcutaneous 100 Mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Kineret		S	Subcutaneous	Solution Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Naproxen		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Prednisone		S	Oral		Not Reported
	Prednisone		S	Unknown		Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Triamcinolone		S	Other		Not Reported
	Triamcinolone Hexacetonide		C	Unknown	Injectable Suspension	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364055	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531428		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported

Desoximetasone	S	Oral	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Golimumab	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364072	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2537099			Male	CAN

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

Apparent Death; Deep Vein Thrombosis; Diverticulitis; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Ilaris	S	Unknown	Single-Use Vial	Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Ilaris	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364086	EXPEDITED (15-DAY)		LT	CA-ROCHE-2537110			Male	CAN

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

Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Ilaris	S	Unknown	Not Reported
	Ilaris	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364135	EXPEDITED (15-DAY)		OT	CA-ROCHE-2534200		41 YR	Female	CAN

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

Hepatic Enzyme Increased; Hepatotoxicity; Treatment Failure	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364139	EXPEDITED (15-DAY)		HO	CA-ROCHE-2534304		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cyst; Deafness Neurosensory; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Aclasta			C				Not Reported
	Actonel			C				Not Reported
	Ergocalciferol			C				Not Reported
	Esomeprazole			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]			C				Not Reported
	Loperamide			C				Not Reported
	Nasonex			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Prednisone			C				Not Reported

	Trazodone	C	Not Reported
	Tylenol	C	Not Reported
	Oxycodone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364143	EXPEDITED (15-DAY)		HO	CA-ROCHE-2534269			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous	100 Mg Per Syringe Single Use		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Triamcinolone Hexacetonide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364184	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533950		83 YR	Female	CAN

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

Blood Creatine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Celebrex	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Fentanyl	S	Unknown		Not Reported
	Gabapentin	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Nortriptyline	S	Oral		Not Reported
	Orencia	S	Vaginal		Not Reported
	Oxycontin	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)		Not Reported
	Actonel	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate	C			Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown		Not Reported
	Loperamide	C			Not Reported
	Nasonex	C	Unknown	Metered Dose	Not Reported
	Oxycodone Terephthalate	C	Unknown		Not Reported
	Pantoprazole Magnesium	C			Not Reported
	Perphenazine	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Trazodone	C			Not Reported
	Tylenol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364199	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533938		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Other			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364233	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533762			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Azathioprine	S	Unknown	Not Reported
	Ciclosporin	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364361	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530616			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364637	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0600			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Leucovorin Calcium			S	Oral			Not Reported
	Cosentyx			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Meloxicam			S	Oral			Not Reported
	Otezla			S	Unknown			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Pantoprazole Magnesium			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Diltiazem Hydrochloride			C	Unknown			Not Reported
	Fluticasone Propionate			C	Unknown			Not Reported
	Mar-Pantoprazole			C	Unknown			Not Reported

Mometasone Furoate	C	Unknown	Not Reported
Premarin	C	Unknown	Not Reported
Salbutamol Sulfate	C	Unknown	Not Reported
Tramadol Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17364672	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0601		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365137	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365159	NON-EXPEDITED			NVSC2020US027808			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Trametinib			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365204	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0625			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365355	EXPEDITED (15-DAY)		LT	CA-ROCHE-2537118			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365404	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532002			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365439	EXPEDITED (15-DAY)		LT	CA-ROCHE-2537126			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365468	NON-EXPEDITED		HO, OT	US-APOTEX-2020AP007164		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroenteritis Cryptosporidial; Neutropenia	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365620	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024416		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Parenteral	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	22 Mg, Qw		Not Reported
	Sulfasalazine			S				Not Reported
	Adalimumab			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			C				Not Reported
	Prednisone			C		6 Mg, Bid		Not Reported
	Minocycline			C				Not Reported

	Penicillamine	C			Not Reported
	Ciclosporin	C			Not Reported
	Azathioprine	C	Unk Unk, Qd		Not Reported
	Actemra	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365621	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA023724			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Hydroxychloroquine Sulfate			S				Sanofi
	Paracetamol			S				Not Reported
	Arava			S				Sanofi
	Sodium Aurothiomalate			S				Not Reported
	Indometacin			S				Not Reported
	Methotrexate			S				Not Reported
	Morphine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S		12.5 Mg, Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Morphine Salt Not Specified			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365622	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024484			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Ill-Defined Disorder; Loss Of	Hydroxychloroquine			S	Unknown			Sanofi
	Plaquenil			S	Oral			Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported

Consciousness; Mobility Decreased	Leflunomide	S	Oral			Sanofi
	Actemra	S	Subcutaneous			Not Reported
	Anakinra	S	Unknown			Not Reported
	Anakinra	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365623	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023865			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Diphenhydramine Hydrochloride			S				Sanofi
	Celecoxib			S	Oral			Not Reported
	Demerol			S				Sanofi
	Levofloxacin			S				Not Reported
	Methotrexate			S				Not Reported
	Azithromycin			S		250 Mg, Qd		Not Reported
	Cyclophosphamide			S		2000 Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S				Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Ezetrol	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365628	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023804			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S	Oral			Sanofi
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S		Unk		Not Reported
	Anakinra			S				Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365629	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023796			Female	CAN

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

Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine Sulfate	S		400 Mg	Sanofi
	Methotrexate	S		20 Mg, Qd	Not Reported
	Leflunomide	S		20 Mg	Sanofi
	Leflunomide	S		20 Mg	Sanofi
	Actemra	S		8 Mg	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S		750 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	C			Not Reported
	Meloxicam	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365630	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA024044			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count Decreased	Hydroxychloroquine			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Acetylsalicylic Acid			S		Unk		Not Reported
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Benzylpenicillin			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Pregabalin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365632	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023787			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S				Not Reported
	Tocilizumab			S				Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Orencia			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow (Solution)		Not Reported
	Enbrel			S				Not Reported
	Cimzia			C	Subcutaneous	Solution		Not Reported
	Prednisone			C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365633	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023682		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S				Sanofi
	Prednisone			S				Not Reported
	Arava			S				Sanofi
	Methotrexate			S		25 Mg 4 Every 1 Week		Not Reported
	Plaquenil			S				Sanofi
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S		162 Mg, Qw		Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365634	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA023772			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disability; Drug Ineffective; Impaired Work Ability; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365635	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024108			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365636	EXPEDITED (15-DAY)		CA, OT	CA-SA-2020SA025775			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Oral	Unk		Not Reported

Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Methotrexate	S	Subcutaneous		Not Reported
	Arava	S	Oral	10 Mg, Qd	Sanofi
	Naproxen	S	Oral	500 Mg, Bid	Not Reported
	Anakinra	S			Not Reported
	Enbrel	S		Unk Unk, Biw	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Naprosyn [Naproxen]	S	Oral	500 Mg, Qd	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S			Not Reported
	Vioxx	S			Not Reported
	Leflunomide	C		10 Mg	Not Reported
	Xeljanz	C	Oral	2 Df, Qd, 5 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365637	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023805		46 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Condition Aggravated; Condition Aggravated; Drug Ineffective; Gait Disturbance; Herpes Zoster; Musculoskeletal Pain; Musculoskeletal Stiffness	Plaquenil			S	Unknown			Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Tramacet			C				Not Reported
	Tramadol			C		100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365638	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023795			Female	CAN

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

Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Plaquenil	S		200 Mg, Bid	Sanofi
	Methotrexate	S		15 Mg, Qw	Not Reported
	Arava	S		20 Mg	Sanofi
	Humira	S	Subcutaneous		Not Reported
	Actemra	S		567 Mg, Qm	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Celebrex	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365639	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA024490		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Hydroxychloroquine			S		400 Mg		Sanofi
	Leflunomide			S	Oral	Unk		Sanofi
	Naproxen			S				Not Reported
	Prednisone			S				Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S				Not Reported
	Orencia			S				Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365641	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024414		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated;	Hydroxychloroquine			S		300 Mg		Sanofi
	Arava			S		20 Mg		Sanofi

Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Arava	S		10 Mg	Sanofi
	Celecoxib	S		50 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Plaquenil	S		300 Mg	Sanofi
	Prednisone	S			Not Reported
	Sulfasalazine	S		2 G	Not Reported
	Enbrel	S		50 Mg, Qw	Not Reported
	Orencia	S	Subcutaneous	250 Mg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365642	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024413		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown	5 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S				Sanofi
	Arava			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Acetaminophen			C				Not Reported
	Cyclobenzaprine			C	Unknown	10 Mg		Not Reported
	Cyclobenzaprine			C	Unknown	10 Mg		Not Reported
	Desoximetasone			C	Unknown	5 Mg, Qd		Not Reported
	Desoximetasone			C	Unknown	5 Mg, Qd		Not Reported

	Leflunomide	C	Unknown		Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Prednisone Acetate	C	Unknown	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365643	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024411		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Synovitis	Hydroxychloroquine			S	Unknown	200 Mg		Sanofi
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Leflunomide			S	Unknown	10 Mg		Sanofi
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365644	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025808			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Plaquenil			S		200 Mg, Qd (2 Every 1 Day)		Sanofi
	Methotrexate			S		20 Mg		Not Reported
	Sulfasalazine			S		1 G, Qd (2 Every 1 Day)		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Humira		S	Subcutaneous		Not Reported
	Orencia		S			Not Reported
	Xeljanz		C	Oral	5 Mg, Qd(2 Every 1 Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365645	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Folic Acid			C	Oral	5 Mg		Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365647	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025492			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Plaquenil			S		200 Mg, Qd		Sanofi
	Sulfasalazine			S		500 Mg, 4 Every 1 Days		Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Rituxan			S	Intravenous (not	1000 Mg		Not Reported

			otherwise specified)	
	Acetaminophen	C	500 Mg	Not Reported
	Hydrocortisone Valerate	C		Not Reported
	Hydromorphone	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Lyderm [Fluocinonide]	C		Not Reported
	Naproxen	C	Unk	Not Reported
	Naproxen	C	250 Mg, Qd	Not Reported
	Prednisone	C	10 Mg, Qd	Not Reported
	Sodium Aurothiomalate	C		Not Reported
	Sodium Aurothiomalate	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365649	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024106		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaphylactic Shock; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain; Synovitis	Hydroxychloroquine			S		400 Mg		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365650	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023794			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Sulfasalazine			S				Not Reported
	Methotrexate			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported

	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Lyrica		C		Not Reported
	Celebrex		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365651	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025786			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Hepatotoxicity	Plaquenil			S		200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S				Sanofi
	Prednisone			S		6 Mg, Qd		Not Reported
	Pregabalin			S		150 Mg, Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Trazodone Hydrochloride			S		25 Mg, Qd		Not Reported
	Xeljanz			S		5 Mg, Bid		Not Reported
	Imuran [Azathioprine Sodium]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365652	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA023870			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Rheumatoid Arthritis	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Unknown			Sanofi
	Indometacin			S	Oral	50 Mg, Qid		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4 Mg/Kg, Q4w		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Q8w	Not Reported
	Indomethacin [Indometacin]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365653	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA025308			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Plaquenil			S		400 Mg, Qd		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Leflunomide			S		Unk Unk, Qd		Sanofi
	Leflunomide			S		Unk		Sanofi
	Orencia			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365654	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023792		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Subcutaneous			Sanofi
	Arava			S	Unknown	10 Mg		Sanofi
	Actemra			S	Unknown	650 Mg, Qm		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown	750 Mg, Qm		Not Reported
	Orencia			S	Subcutaneous	250 Mg		Not Reported
	Rituxan			S	Subcutaneous	1000 Mg		Not Reported
	Methotrexate			C	Unknown	20 Mg, Qw		Not Reported
	Prednisone			C		250 Mg		Not Reported
	Prednisone			C		40 Mg		Not Reported

	Sulfasalazine	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365655	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025330			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S				Sanofi
	Plaquenil			S				Sanofi
	Doxycycline			S		50 Mg		Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Rituximab			S				Not Reported
	Methotrexate			C		25 Mg		Not Reported
	Prednisone			C		10 Mg, Qd		Not Reported
	Simponi			C	Subcutaneous	50 Mg, Qm		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365656	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023721			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate			S				Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Aspirine			S				Not Reported
	Leflunomide			S	Oral			Sanofi
	Methotrexate			S				Not Reported
	Procaine Benzylpenicillin			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Pregabalin			C				Not Reported
	Xeljanz			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365658	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024419		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Decreased; Weight Increased	Hydroxychloroquine Sulfate			S				Sanofi
	Plaquenil			S				Sanofi
	Amlodipine Besilate			S	Oral	5 Mg, Qd		Not Reported
	Amlodipine Besilate			S	Oral	Unk Unk, Qd		Not Reported
	Amlodipine Besilate			S	Unknown	Unk		Not Reported
	Asacol			S	Unknown	800 Mg, Tid		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Gliclazide			S	Unknown			Not Reported
	Enbrel			S		50 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S				Not Reported
	Atacand Plus			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Diphenhydramine			C	Oral	50 Mg		Not Reported
	Ebastine			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Mg		Not Reported

Rosuvastatin Calcium	C		Not Reported
Tylenol	C		Not Reported
Vitamin D3	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365659	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025326			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solutions)		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365660	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025296			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Visual Impairment	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Sulfasalazine			S	Oral	1 G, Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutanoeus		Not Reported

	Orencia	S	Unknown		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365661	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023774			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		300 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S		200 Mg, Qw		Not Reported
	Methotrexate			S		15 Mg; Qw		Not Reported
	Methotrexate			S		20 Mg; Qw		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		25 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C	Oral			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365662	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023786		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain;	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi

Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine		S	Oral	200 Mg, Bid	Sanofi
	Hydroxychloroquine		S	Unknown	200 Mg	Sanofi
	Prednisone		S	Oral	5 Mg, Qd	Not Reported
	Prednisone		S	Oral	5 Mg, Qd	Not Reported
	Methotrexate		S	Oral	200 Mg, Qw	Not Reported
	Methotrexate		S	Subcutaneous	200 Mg	Not Reported
	Sulfasalazine		S	Unknown	1000 Mg, Bid	Not Reported
	Leflunomide		S	Unknown	20 Mg, Qd	Sanofi
	Orencia		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous	50 Mg	Not Reported
	Humira		S	Subcutaneous	20 Mg, Qd	Not Reported
	Actemra		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365663	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025759			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Hydroxychloroquine			S		Unk		Sanofi
	Pregabalin			S		Unk		Not Reported
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Mirtazapine			S		15 Mg		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365664	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023776			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S				Sanofi
	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Pregabalin			S				Not Reported
	Actemra			S				Not Reported
	Cellcept [Mycophenolate Mofetil Hydrochloride]			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S				Not Reported
	Prednisone			C				Not Reported
	Piroxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365665	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025313			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Plaquenil			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S		Unk		Not Reported

	Remicade	S		Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Stelara	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365666	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA024082			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Plaquenil			S		200 Mg, Bid		Sanofi
	Leflunomide			S	Oral	10 Mg		Sanofi
	Leflunomide			S	Oral	10 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Cefazolin			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Naproxen			C		500 Mg		Not Reported
	Viread			C				Not Reported
	Xeljanz			C	Oral	5 Mg		Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365667	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA023793			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Alendronate Sodium			S	Unknown	70 Mg, Qw		Not Reported

Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Skin Ulcer	Codeine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Sanofi
	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Actemra	S		360 Mg, Qm	Not Reported
	Enbrel	S		25 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Ciclosporin	C		150 Mg, Qd	Not Reported
	Prednisone	C		10 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365668	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024418			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea; Off Label Use	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Plaquenil Sulfate			S		400 Mg, Qd		Sanofi
	Arava			S	Unknown			Sanofi
	Methotrexate			S		25 Mg		Not Reported
	Enbrel			S	Unknown	50 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Q4w		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365669	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024036		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Transaminases Abnormal	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365680	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023790			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Intolerance; Interstitial Lung Disease; Pulmonary Mass; Sinusitis; Synovitis	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown	Tablets		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Cosentyx			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365681	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025307			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Drug Ineffective; Drug	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi

Intolerance; Drug Tolerance Decreased; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Prescribed Underdose; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Vomiting; X-Ray Abnormal	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown	10 Mg	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Unknown		Sanofi
	Methotrexate	S	Oral	20 Mg, Qw	Not Reported
	Leflunomide	S	Unknown		Sanofi
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1 Df	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365682	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA025328			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Arava			S		10 Mg, Qd		Sanofi
	Paracetamol			S	Endocervical			Not Reported
	Plaquenil			S		200 Mg, Bid		Sanofi
	Prednisone			S	Oral	20 Ng		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported

Sulfasalazine	S	Oral	2000 Mg		Not Reported
Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
Enbrel	S		50 Mg, Qw		Not Reported
Humira	S	Subcutaneous			Not Reported
Orencia	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution		Not Reported
Simponi	S	Subcutaneous			Not Reported
Methotrexate	C		20 Mg, Qw Solution		Not Reported
Methotrexate	C		25 Mg, Qw		Not Reported
Methotrexate	C		Unk, Q4w		Not Reported
Meloxicam	C				Not Reported
Synthroid	C				Not Reported
Acetaminophen And Codeine Phosphate	C				Not Reported
Actemra	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17365683	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA024415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Off Label Use; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus	Hydroxychloroquine			S		400 Mg		Sanofi
	Actemra			S	Unknown			Not Reported
	Leflunomide			S		10 Mg, Qd		Sanofi
	Cimzia			S	Subcutaneous			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

Erythematosus Rash; Tenosynovitis; Therapeutic Response Decreased; Tooth Disorder; Tooth Infection; Weight Decreased	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Q4w	Not Reported
	Prednisone	S	Unknown		Not Reported
	Risedronate Sodium	C		35 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17366989	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020043725		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Mg, Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17366993	EXPEDITED (15-DAY)		HO, LT	FR-ELI_LILLY_AND_COMPANY-FR202001013747		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Interaction; Dyspnoea; Feeling Abnormal; Head Discomfort; Palpitations; Reading Disorder	Fluoxetine Hydrochloride			S	Unknown	1 Df, Qd, Tablet		Eli Lilly And Co
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17367375	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020048559		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S		Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17367657	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1178949			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Off Label Use	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17367697	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1178528		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Prednisone			C	Oral	17 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17367722	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179082		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign; Off Label Use; Product Use In Unapproved Indication	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Ciclosporin			S	Unknown			Ivax

	Alendronate Sodium	S	Unknown	Actavis
	Calcium Carbonate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Barr
	Leflunomide	S		Barr
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Acetazolamide	S	Unknown	Not Reported
	Ferric Hydroxide Polymaltose Complex	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17367888	NON-EXPEDITED			US-PFIZER INC-2020044225		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Codeine Sulfate			S		Unk		Not Reported
	Yodoxin			S		Unk		Not Reported
	Augmentin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	17369219	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016056029		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen

Arava	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	5 Milligram	Not Reported
Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	0.8 Milligram	Not Reported
Apo-Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Methotrexate Sodium	S	Unknown	20 Mg, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	15 Milligram	Not Reported
Orencia	S	Unknown	750 Mg, Q4wk	Not Reported
Orencia	S	Unknown	750 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	5 Mg, Q8wk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Certolizumab Pegol	C	Unknown	Unk	Not Reported

Tofacitinib	C		Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Simponi	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	12538837	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016070695		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Milligram, Qd		Not Reported
	Apo-Hydroxyquine			S	Oral	200 Milligram, Bid		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Oral	200 Milligram, Qd		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Oral	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate			C	Oral	20 Milligram, Qwk		Not Reported

	Methotrexate	C	Oral	Unk, Q2wk	Not Reported
	Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported
	Hydroxychloroquine	C	Oral	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	C	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Oral	400 Milligram, Qwk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisone	C	Oral	Unk	Not Reported
	Folic Acid	C	Oral	5 Milligram, Qd (6 Days Per Week)	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Leflunomide	C	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	12705597	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1521		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Contraindicated Product Administered; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Impaired Work Ability; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported

Treatment Failure; Vein Disorder	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Humira	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Fosamax	C	Unknown	Not Reported
	Ibuprofen	C	Unknown	Not Reported
	Lisinopril	C	Unknown	Not Reported
	Vit D3	C	Unknown	Not Reported
	Alendronate Sodium	C	Unknown	Not Reported
	Fosavance	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Mtx	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	12774372	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076813		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Frustration Tolerance Decreased; Ill-Defined Disorder; Impaired Work	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram		Not Reported

Ability; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling; Treatment Failure; Vein Disorder	Folic Acid	S	Unknown		Not Reported
	Enbrel	S	Unknown	50.0 Milligram	Not Reported
	Gold	S	Unknown	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	5.0 Milligram	Not Reported
	Fosamax	C	Unknown	Unk	Not Reported
	Ibuprofen	C	Unknown	Unk	Not Reported
	Lisinopril	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Alendronate Sodium	C	Unknown	Unk	Not Reported
	Fosavance	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	13162393	EXPEDITED (15-DAY)		OT	CA-ROCHE-1884997		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown	Therapy Duration: 976.0	Not Reported
	Methotrexate Sodium	S	Unknown	Therapy Duration: 9.0 Year(S)	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 10.0 Year(S)	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Rituxan	C	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	13923554	EXPEDITED (15-DAY)		HO, LT, OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2654		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein	Methotrexate (Trade Name Unknown)			S				Not Reported
	Enbrel			S	Unknown			Not Reported

Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Enbrel	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Apo-Sulfasalazine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported

	Sodium Aurothiomalate	S			Not Reported
	Rituximab	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	15272092	EXPEDITED (15-DAY)		HO	US-TEVA-2018-US-943473		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Hypokalaemia; Overdose	Hydroxychloroquine			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	15400613	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186061			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Wellbutrin	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	15470065	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2018M1073020		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Hyperprolactinaemia; Myopathy; Orthostatic Hypotension	Itraconazole			S	Oral	100 Mg, Qd		Not Reported
	Lansoprazole			S	Unknown	30 Mg, Qd		Not Reported
	Risedronate			S	Unknown	35 Mg, Unk		Not Reported
	Theophylline			S	Unknown	200 Milligram, Bid		Not Reported
	Levothyroxine			S	Unknown	75 Microgram, Qd		Not Reported
	Prednisolone			S	Unknown	7.5 Milligram, Qd		Not Reported
	Domperidone			S	Unknown	10 Milligram, Q8h,30 Mg, Qd (10 Mg, Tid)		Mylan
	Amylase/Lipase/Protease			S	Unknown	10 Milligram, Tid		Mylan
	Carbocisteine			S	Unknown	750 Milligram, Bid,750 Milligram (750mg 2 Tds)		Mylan
	Immunoglobulins Nos			S	Unknown	Unk		Mylan
	Creon			S	Unknown	10 Milligram, Q8h, (30 Milligram, Qd, 10 Mg, Tid)		Mylan
	Uniphyllin			S	Unknown	400 Milligram, Qd (200 Mg, Bid)		Mylan
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Mylan

	Propanolol /00030001/	C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	15500678	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018024121		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Bactrim			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	15582761	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1028			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Ulcer; Inflammation; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Pruritus; Rheumatoid Arthritis;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	4 Times A Week		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported

Rheumatoid Factor Positive; Synovitis	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	16088849	EXPEDITED (15-DAY)		OT	PHHY2019CA056635			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	16783313	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-084437		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache;	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Gold			S	Unknown			Not Reported

Infection; Off Label Use; Pharyngeal Oedema; Rheumatoid Arthritis	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Arava	S	Unknown	20 Milligram	Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	16863631	EXPEDITED (15-DAY)		OT	PT-JNJFOC-20190929486		63 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Interstitial Lung Disease; Off Label Use; Product Use In Unapproved Indication; Pulmonary Embolism; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown	Twice 2 Weeks Apart, Cyclic (9 Cycles)		Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17245651	EXPEDITED (15-DAY)		OT	FR-ROCHE-2513203		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis; Hyperkeratosis; Ocular Toxicity	Mycophenolate Mofetil			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17263011	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1001517		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster; Herpes Zoster Meningitis; Lung Neoplasm Malignant	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Prednisolone			S	Oral	5 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	2 Dosage Form, Qd		Mylan
	Imeth /00113801/			S	Subcutaneous	10 Milligram, Qw		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17296572	EXPEDITED (15-DAY)		OT	TN-APPCO PHARMA LLC-2079273			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Toxic Skin Eruption	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17296604	EXPEDITED (15-DAY)		DE, OT	TN-APPCO PHARMA LLC-2079274			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Haemophagocytic Lymphohistiocytosis	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17296702	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-PFIZER INC-2020025201			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During	Fluconazole			S	Transplacental	Unk		Pfizer

Pregnancy; Oligohydramnios; Premature Baby	Methylprednisolone	S	Transplacental	Unk	Pfizer
	Methylprednisolone	S	Transplacental	Unk	Pfizer
	Vitamin K Nos	S	Transplacental	Unk	Not Reported
	Bisulepin	S	Transplacental	Unk	Not Reported
	Nadroparine	S	Transplacental	Unk	Not Reported
	Etamsylate	S	Transplacental	Unk	Not Reported
	Privigen	S	Transplacental	Unk	Not Reported
	Flebogamma Dif	S	Transplacental	Unk	Not Reported
	Dexamethasone	S	Transplacental	Unk	Not Reported
	Dexamethasone	S	Transplacental	Unk	Not Reported
	Metoprolol Tartrate	S	Transplacental	Unk	Not Reported
	Potassium Chloride	S	Transplacental	Unk	Not Reported
	Prednisone	S	Transplacental	Unk	Not Reported
	Prednisone	S	Transplacental	Unk	Not Reported
	Vitamin B Complex	S	Transplacental	Unk	Not Reported
	Albumin	S	Transplacental	Unk	Not Reported
	Paracetamol	S	Transplacental	Unk	Not Reported
	Calcium Carbonate	S	Transplacental	Unk	Not Reported
	Ornidazole	S	Transplacental	Unk	Not Reported
	Cefixime	S	Transplacental	Unk	Not Reported
	Magnesium Lactate	S	Transplacental	Unk	Not Reported
	Bisoprolol Fumarate	S	Transplacental	Unk	Not Reported
	Folic Acid	S	Transplacental	Unk	Not Reported
	Omeprazole	S	Transplacental	Unk	Not Reported
	Cefotaxime	S	Transplacental	Unk	Not Reported
	Cefotaxime	S	Transplacental	Unk	Not Reported
	Hydroxychloroquine	S	Transplacental	Unk	Not Reported
	Hydrocortisone	S	Transplacental	Unk	Not Reported
	Vulmizolin	S	Transplacental	Unk	Not Reported

	Penicillin G	S	Transplacental	Unk	Not Reported
	Aminomethylbenzoic Acid	S	Transplacental	Unk	Not Reported
	Vitamin D	S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17363211	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532630			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Lozide [Indapamide]			C	Unknown			Not Reported
	Metformin			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

	Acetylsalicylic Acid	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Lantus	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17369757	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538294			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370217	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179028			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva

Impairment	Prednisone		S	Unknown	Actavis
	Anakinra		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370247	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179012		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Asthma; Back Pain; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Hypertension; Inflammation; Pain; Septic Shock; Synovitis; Urinary Tract Infection; Urosepsis	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Salicylates Nos			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370250	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1179312			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Azathioprine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	3 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370276	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-210851		36 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Phospholipidosis	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Sun
	Ramipril			S	Unknown	Unk		Ranbaxy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370297	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020047519		29 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; X-Ray Abnormal	Methotrexate Sodium			S	Unknown	10 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Daily		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Daily		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370526	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179211			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Diverticulitis; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown	3000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370545	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179284			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Azathioprine			S	Unknown	150 Milligram Daily;		Not Reported
	Ciclosporin			S	Unknown			Actavis
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Doxycycline Hyclate			S	Unknown			Actavis
	Mercaptopurine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Methylprednisolone			S	Unknown			Actavis
	Bromocriptine			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Pamidronate Disodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tenoxicam			S	Unknown			Not Reported
	Ustekinumab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370549	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179426			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug	Azathioprine			S	Unknown			Not Reported

Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose	Methotrexate	S	Subcutaneous	Barr
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370571	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2533713			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting			otherwise specified)		
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370612	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370736	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201901-000023			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chorioretinopathy	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia

	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	200 Mg, Qd	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	200 Mg/Day And 400 Mg/Day, Alternately	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	200 Mg/Day And 400 Mg/Day, Alternately	Concordia
	Prednisolone	S	Oral	10 Mg, Qd	Not Reported
	Onealfa	C		Unk	Not Reported
	Onealfa	C			Not Reported
	Takepron	C		Unk	Not Reported
	Takepron	C			Not Reported
	Persantin	C		Unk	Not Reported
	Epadel T	C		Unk	Not Reported
	Bonalon	C		Unk	Not Reported
	Bonalon	C			Not Reported
	Loxonin	C		Unk	Not Reported
	Selbex	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17370807	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533766		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Infusion Related Reaction; Knee	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cortisone			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported
	Desoximetasone			S	Oral			Not Reported

Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone	S	Cutaneous	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Sunconjunctival	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17371160	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538246		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Celebrex	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Diclofenac Potassium	S	Unknown	Not Reported
	Dilaudid	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17371199	EXPEDITED (15-DAY)		HO, OT	CA-ASTELLAS-2018US049131		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; Drug Ineffective; Fungal Infection; Nodule; Osteomyelitis; Rash; Systemic Infection; Systemic Mycosis	Amphotericin B, Liposome			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Astellas
	Amphotericin B, Liposome			S	Intravenous (not otherwise specified)			Astellas
	Voriconazole			S	Oral			Not Reported
	Voriconazole			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Azathioprine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			S	Unknown	40 Mg, Once		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17371228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531864		38 YR	Female	CAN

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

Bedridden; Crying; Drug Ineffective	Actemra		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Ergocalciferol		C	Unknown	Not Reported
	Leucovorin [Folinic Acid]		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17371763	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536707			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Oxycodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372026	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179418			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Dysphagia; Gastrointestinal Disorder;	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr

Hepatitis; Muscle Disorder; Skin Disorder	Mycophenolate Mofetil		S	Unknown	2 Gram Daily;	Teva
	Prednisone		S	Unknown		Actavis
	Hydroxychloroquine		S	Oral	200 Milligram Daily;	Not Reported
	Myfortic		S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372069	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1179359		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tacrolimus			S	Unknown	6 Dosage Forms Daily;		Not Reported
	Tacrolimus			S	Unknown	5 Dosage Forms Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral	17 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372076	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179282		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372079	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179232			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Headache; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Stomatitis; Tinnitus	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372123	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025321			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Joint Swelling; Treatment Failure	Plaquenil			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw, Solution		Not Reported
	Arava			S		Tablet		Sanofi
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported

U.S. FOOD & DRUG ADMINISTRATION

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372133	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023785		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	300 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qw		Sanofi
	Actemra			S		50 Mg, Qw		Not Reported
	Actemra			S		4.0 Mg/Kg		Not Reported
	Adalimumab			S		Unk		Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S		40 Mg		Not Reported
	Orencia			S		Unk Unk, Qm		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S		1 G		Not Reported
	Rituximab			S		1 G		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S				Not Reported
	Celebrex			C				Not Reported
	Diclofenac			C				Not Reported
	Lyrica			C				Not Reported
	Methotrexate			C	Subcutaneous	20 Mg, Qw		Not Reported
	Methotrexate			C		0.8 Ml, Qw		Not Reported

Sulfasalazine	C				Not Reported
Tocilizumab	C	Endocervical			Not Reported
Valsartan	C				Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Methotrexate	C	Oral	Unk Unk, Qw		Not Reported
Methotrexate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372135	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA025298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine Sulfate			S		400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Naproxen			S				Not Reported
	Prednisone			S				Not Reported
	Naproxen Sodium			S	Oral			Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Tocilizumab			S				Not Reported
	Xeljanz			S		5 Mg, 2 Every 1 Day		Not Reported
	Orencia			S				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C		Form: Solution		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372138	EXPEDITED (15-DAY)		OT	CA-SA-2020SA024488		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida	Hydroxychloroquine			S		300 Mg		Sanofi

Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Methotrexate	S	Subcutaneous	25 Mg		Not Reported
	Methotrexate	S	Subcutaneous	20 Mg		Not Reported
	Methotrexate	S	Subcutaneous	25 Mg		Not Reported
	Methotrexate	S	Subcutaneous	10 Mg		Not Reported
	Arava	S				Sanofi
	Sulfasalazine	S		2 Mg		Not Reported
	Celecoxib	S				Not Reported
	Leflunomide	S		10 Mg		Sanofi
	Prednisone	S				Not Reported
	Orencia	S	Subcutaneous	250 Mg		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Enbrel	S	Subcutaneous	50 Mg, 1 Every 1 Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372139	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025415			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S				Sanofi
	Doxycycline			S		50 Mg		Not Reported
	Leflunomide			S		20 Mg, Qd (1 Every 1 Day)		Sanofi
	Plaquenil			S		Unk		Sanofi
	Doxycycline Hyclate			S		50 Mg		Not Reported
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Simponi			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372147	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025784		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Hydroxychloroquine			S		300 Mg		Sanofi
	Arava			S				Sanofi
	Leflunomide			S	Oral	10 Mg		Sanofi
	Celecoxib			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Methotrexate			S	Subcutaneous	2.5 Mg		Not Reported
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S		2 Mg		Not Reported
	Folic Acid			C		10 Mg, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C				Not Reported
	Simponi			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372151	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179046			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Feeling Abnormal; Rheumatoid Arthritis; Thirst	Azathioprine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr

Arava	S	Unknown	20 Milligram Daily;		Not Reported
Enbrel	S	Unknown			Not Reported
Plaquenil	S	Unknown			Not Reported
Xeljanz	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372160	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023783			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Plaquenil			S		200 Mg, Bid		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Sulfasalazine			S	Oral	2000 Mg		Not Reported
	Acetaminophen			S				Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S		50 Mg, Qiw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen;Codeine Phosphate			C				Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C		25 Mg, Qw		Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372164	EXPEDITED (15-DAY)		OT	CA-SA-2020SA025798			Female	CAN

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

Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine	S		400 Mg	Sanofi
	Hydroxychloroquine	S		200 Mg, 2 Every 1 Weeks	Sanofi
	Hydroxychloroquine	S		200 Mg	Sanofi
	Hydroxychloroquine	S		400 Mg	Sanofi
	Hydroxychloroquine	S		200 Mg 2 Every 1week	Sanofi
	Hydroxychloroquine	S		400 Mg, 3 Every 1 Weeks	Sanofi
	Leflunomide	S			Sanofi
	Methotrexate	S		20 Mg, Qw	Not Reported
	Leflunomide	S		Unk	Sanofi
	Sulfasalazine	S			Not Reported
	Orencia	S			Not Reported
	Enbrel	S		50 Mg, Qw	Not Reported
	Enbrel	S		50 Mg	Not Reported
	Adalimumab	S		40 Mg, 1 Every 2 Weeks	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg	Not Reported
	Actemra	S	Subcutaneous	162 Mg 2 Every 1 Weeks	Not Reported
	Actemra	S		162 Mg	Not Reported
	Prednisone	C		20 Mg, Qd	Not Reported
	Xeljanz	C		5 Mg, 2 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372171	EXPEDITED (15-DAY)		HO	CA-ROCHE-2530390		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Vaginal			Not Reported

Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Myochrysine	S	Intramuscular	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Celebrex	S	Oral	Not Reported
	Aclasta	C	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported
	Ergocalciferol	C		Not Reported
	Esomeprazole	C		Not Reported
	Ferrous Gluconate	C	Unknown	Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	Not Reported
	Loperamide	C		Not Reported
	Nasonex	C		Not Reported
	Nortriptyline	C	Unknown	Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]	C		Not Reported
	Oxycodone Terephthalate	C		Not Reported
	Perphenazine	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Trazodone Hydrochloride	C	Unknown	Not Reported
	Tylenol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372473	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1179363		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer; Thrombosis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva

Plaquenil	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tacrolimus	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17372538	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1013147		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cryptosporidiosis Infection; Hypogammaglobulinaemia; Leukopenia; Neutropenia; Weight Decreased	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17373082	EXPEDITED (15-DAY)		OT	NVSC2020US027795			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Malignant Neoplasm Progression; Pancreatic Carcinoma; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Trametinib			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17373885	EXPEDITED (15-DAY)		OT	TN-APPCO PHARMA LLC-2079842			Unknown	TUN

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

Drug Eruption; Toxic Skin Eruption	Hydroxychloroquine Sulfate		S	Unknown	Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17374167	EXPEDITED (15-DAY)		OT	TN-APPCO PHARMA LLC-2079843			Unknown	TUN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Toxic Skin Eruption	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17374926	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020047444		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Glucose Increased; C-Reactive Protein Increased; Chest Discomfort; Dizziness; Dyspnoea; Gastrointestinal Disorder; Influenza; Joint Swelling; Lung Disorder; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Neck Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Sarcoidosis; Sensory Loss; Therapeutic Response Decreased; Tuberculosis; Urinary Tract Infection; Vision Blurred; White Blood Cells Urine Positive	Methotrexate Sodium			S	Unknown			Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Unk		Not Reported
	Isoniazid			S	Unknown			Not Reported
	Prednisone			S	Unknown	7.5 Mg, Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	500 Mg, 1 Every 2 Weeks		Not Reported
	Acetaminophen			C	Oral	650 Mg, Unk		Not Reported
	Azathioprine			C				Not Reported
	Diphenhydramine Hydrochloride			C				Not Reported
	Folic Acid			C				Not Reported
	Glyburide			C				Not Reported
	Glyburide			C		Unk		Not Reported
	Metformin			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Pariet			C				Not Reported
	Ramipril			C				Not Reported

Synthroid	C		Not Reported
Trajenta	C		Not Reported
Vitamin B6	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2020	17374991	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538100		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Solutiuon		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration- 730.0		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	11761994	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015241187		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Creatinine Decreased; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache;	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Cyclic: 4 Times/Week		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Unknown

Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Tinnitus; Vision Blurred; White Blood Cell Count Decreased	Methotrexate Sodium	S	Unknown	25 Mg, Weekly	Pfizer
	Hydromorphone Hydrochloride	S		Unk	Unknown
	Folic Acid	S		5 Mg, Unk	Not Reported
	Folic Acid	S		15.5 Unk	Not Reported
	Plaquenil Sulfate	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	520 Mg, Q4wk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	520 Milligram	Not Reported
	Acetaminophen	S	Oral	65 Mg, Unk	Not Reported
	Acetaminophen	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	7.5 Mg, Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Dilaudid	S	Unknown	Unk	Not Reported
	Apo-Acetaminophen	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	300 Mg, Qd	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Diphenhydramine Hydrochloride	C	Oral	50 Mg, Unk	Not Reported
	Fosavance	C		Unk Unk, Qwk	Not Reported
	Hydrocortisone	C	Intravenous (not otherwise specified)	250 Mg, Unk	Not Reported
	Hyzaar	C		12.5 Mg, Qd	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	12327018	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2013020048		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; Bone Erosion; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Physical Disability; Rheumatoid Arthritis; Spinal Operation; Surgery; Thrombocytosis	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	500 Milligram, Bid		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	125 Milligram, Qwk		Not Reported
	Apo-Methotrexate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Abatacept			S	Subcutaneous	125 Milligram		Not Reported
	Prednisone			S	Unknown	20 Milligram A Day		Not Reported
	Prednisone			S	Unknown	2.5 Milligram, Qwk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naprelan			C		1000 Milligram, Qd		Not Reported
	Folic Acid			C		5 Milligram, 4 Times/Wk		Not Reported
	Crestor			C		Unk		Not Reported
	Metoprolol			C		50 Milligram		Not Reported

Gabapentin	C	Unknown	Unk	Not Reported
Lovastatin	C	Unknown	Unk	Not Reported
Vitamin D	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Tramadol Hydrochloride	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Naproxen	C	Unknown	500 Milligram, Bid	Not Reported
Naproxen Sodium	C	Unknown	1000 Milligram, Qd	Not Reported
Rosuvastatin Calcium	C		Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Rosuvastatin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	12480786	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016249481		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Incorrect Route Of Product Administration; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Rituximab			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Simponi	S	Subcutaneous	Unk		Not Reported
	Apo Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	12908779	EXPEDITED (15-DAY)		HO, LT, OT	CA-BAXALTA-2016BLT007821			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	Unk		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram, Unknown		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram, Unknown		Shire
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram, Unknown		Shire
	Abatacept			S	Intravenous (not otherwise specified)	200 Mg, 1x A Month		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	50 Milligram, Unknown		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, 1x/Day:Qd		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, 1x/Week		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	1 Dosage Form, 1x/Day:Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Unknown		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, 2x A Week		Not Reported

Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting	Enbrel	S	Subcutaneous	25 Milligram, Unknown	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg, 1x A Week	Not Reported
	Enbrel	S	Subcutaneous	4 Dosage Form, 1x/Week	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, 1x/Day:Qd	Not Reported
	Hydroxychloroquine	S	Oral	1 Dosage Form, 1x/Day:Qd	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3.0 Mg/Kg, Every 6 Wk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk Unk, Every 6 Wk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Milligram, Unknown	Not Reported
	Infliximab	S	Unknown	1 Dosage Form, 1x/Day:Qd	Not Reported
	Methotrexate	S	Unknown	15 Mg/M2, 1x A Week	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, 1x/Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, 1x/2wks	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	15 Mg/M2, 1x A Week	Not Reported
	Methotrexate	S	Subcutaneous	4 Dosage Form, 1x/Week	Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Apo-Naproxen	S			Not Reported
	Apo-Prednisone	S	Oral	50 Mg, Tablet	Not Reported
	Apo-Prednisone	S	Oral	1.3 Milligram, 2x/Day:Bid	Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, 2x/Day:Bid	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, 2x/Day:Bid	Not Reported

Sulfasalazine	S	Oral	250 Mg, 1x A Day	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, 2x A Week	Not Reported
Tocilizumab	S			Not Reported
Triamcinolone	S	Unknown	Spray Metered Dose	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 1x/Week	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 1x/2wks	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, 1x/2wks	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1 Every 2 Months	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1 Dosage Form, 1x A Month	Not Reported
Prednisone	S	Unknown	50 Milligram	Not Reported
Prednisone	S	Oral	50 Milligram, 2x/Day:Bid	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	1.3 Milligram, 2x/Day:Bid	Not Reported
Prednisone	S	Oral	1.3 Milligram, 2x/Day:Bid	Not Reported
Prednisone	S	Oral	3 Milligram, 2x/Day:Bid	Not Reported

Prednisone	S	Oral	2 Dosage Form, 1x/Day:Qd		Not Reported
Triamcinolone Acetonide	S	Unknown	Unk		Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unk		Not Reported
Triamcinolone Hexacetonide	S	Other	Unk		Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unk		Not Reported
Folic Acid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	13107350	EXPEDITED (15-DAY)		OT	CA-ROCHE-1877114			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Stomatitis; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	For 8 Months		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	13113133	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0862		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Prescribed Underdose; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	13114444	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20170105843		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adverse Event; Alanine Aminotransferase Increased; Ankylosing Spondylitis; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Asthma; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Blood Test Abnormal; Body Temperature Decreased; Bone Lesion; C-Reactive Protein Increased; Cataract; Chest Pain; Chills; Contraindicated Product Administered; Contusion; Deep Vein Thrombosis; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dysphonia; Dyspnoea; Erythema; Fall; Fatigue;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous	Start Date: 5th Of Unspecified Month		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous	Start Date: 1st Of Unspecified Month		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Start Date: 8th Of Unspecified Month		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

Feeling Abnormal; Gastrointestinal Disorder; Gastrointestinal Pain; Granuloma Skin; Heart Rate Increased; Hepatic Enzyme Abnormal; Hypercalcaemia; Infection; Inflammation; Influenza; Infusion Related Reaction; Lethargy; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Morton'S Neuralgia; Muscular Weakness; Musculoskeletal Disorder; Musculoskeletal Stiffness; Mycotic Allergy; Nausea; Neuropathy Peripheral; Oral Discomfort; Pain; Pain In Extremity; Panniculitis; Peripheral Swelling; Product Use Issue; Productive Cough; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Respiratory Tract Congestion; Rheumatoid Arthritis; Rheumatoid Nodule; Rhinorrhoea; Skin Necrosis; Skin Ulcer; Speech Disorder; Ulcer	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	Start Date: On 10th Of Unspecified Month In 2011.	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Alendronate	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral	4 Years	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)		Not Reported
	Codeine	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Start Date: 1st Of Unspecified Month	Not Reported
	Methotrexate	S	Unknown	Start Date: 5th Of	Not Reported

			Unspecified Month	
Methotrexate	S	Unknown	Start Date: 5th Of Unspecified Month	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown	Start Date: 1st Of Unspecified Month	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Parenteral		Not Reported
Orencia	S	Unknown	Start Date: 1st Of Unspecified Month	Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Rituximab	S	Unknown		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Alendronic Acid	S			Not Reported
Leflunomide	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Cosentyx	S	Subcutaneous		Not Reported
Cosentyx	S	Subcutaneous		Not Reported

	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Cosentyx	S	Subcutaneous	Not Reported
	Ergocalciferol	S	Unknown	Not Reported
	Pantoprazole	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisolone	C		Not Reported
	Desoximetasone	C		Not Reported
	Naproxen	C		Not Reported
	Plaquenil /00072602/	C		Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Sulfasalazine	C		Not Reported
	Symbicort	C		Not Reported
	Tramadol Hydrochloride	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	13136489	EXPEDITED (15-DAY)		OT	CA-ROCHE-1882213		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	13224604	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890646		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Prednisone Acetate			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	13231930	NON-EXPEDITED		OT	US-VALIDUS PHARMACEUTICALS LLC-US-2016VAL000196			Unknown	USA

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

Anaphylactic Reaction; Hypersensitivity; Nausea; Vomiting	Lasix		S	Unknown	Unk	Validus
	Plaquenil /00072602/		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	14335835	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2163		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	14746831	EXPEDITED (15-DAY)		HO	CA-ROCHE-2104630		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Decreased; Headache; Injection Site Reaction; Joint Swelling; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Methotrexate		S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Xeljanz		S	Unknown		Not Reported
	Arava		C	Oral		Not Reported
	Orencia		C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15227435	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016285040		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Arava			S	Oral	200 Mg, 1x/Day		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Mg, 1x/Day		Not Reported

Apo-Hydroxyquine	S	Oral	400 Mg, 1x/Day (200 Mg 2 Tablet)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Mg, Bid	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Oral	200 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Folic Acid	C	Oral	5 Mg, 1x/Day (6 Days Per Week)	Not Reported
Folic Acid	C	Oral	5 Mg, 1x/Day	Not Reported
Prednisone	C	Oral	Unk	Not Reported
Leflunomide	C	Oral	20 Mg, 1x/Day	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Oral	200 Mg, Bid	Not Reported
Hydroxychloroquine	C	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Oral	400 Milligram, Qwk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported
Methotrexate	C	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	C	Oral	Unk, Q2wk	Not Reported
Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15231584	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015216365		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Product Use Issue; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk (Powder For Suspension)		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15286201	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20180803503		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous	400 Milligram		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported

	Simponi	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15395851	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186085		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15448137	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189248		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15517815	NON-EXPEDITED		OT	CA-AMGEN-CANSL2017166286		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Subcutaneous	200 Milligram, Q2wk		Amgen
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Q2wk		Not Reported

Decreased; Tuberculin Test Positive	Cimzia		S	Subcutaneous	200 Milligram, Cyclical	Not Reported
	Cimzia		S	Subcutaneous	200 Milligram	Not Reported
	Humira		S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira		S	Subcutaneous	40 Milligram, Cyclical	Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Xeljanz		S	Oral	5 Milligram, Bid	Not Reported
	Methotrexate		S	Unknown	5 Milligram	Not Reported
	Leflunomide		S	Oral	5 Milligram	Not Reported
	Leflunomide		S	Oral	10 Milligram	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Leflunomide		S	Oral	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	5 Milligram	Not Reported
	Orencia		S	Unknown	750 Milligram	Not Reported
	Orencia		S	Unknown	750 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	5 Milligram	Not Reported
	Prednisone		C	Unknown	50 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15668198	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570721-00		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Off Label Use;	Humira			S	Subcutaneous			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Asacol			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Amlodipine	S	Oral	Not Reported
	Depo-Medrol	S	Intra-articular	Not Reported
	Depo-Medrol	S		Not Reported
	Mesalazine	S	Oral	Not Reported
	Atacand Plus	C	Oral	Not Reported
	Bisoprolol Fumarate	C	Oral	Not Reported
	Ferrous Gluconate	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Omega Allergenic Extracts	C	Intradermal	Not Reported
	Tylenol	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15675190	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573931-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Arthritis Bacterial; Device Related Sepsis; Drug Ineffective; Drug Intolerance; Gastric Disorder; Mobility Decreased; Nerve Injury; Neurological Procedural Complication; Pain; Post Procedural Complication; Procedural Complication; Rheumatoid Arthritis; Therapeutic Response Decreased	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Plaquenil			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15712231	EXPEDITED (15-DAY)		HO, OT	CA-ASTELLAS-2018US052428		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Tacrolimus			S	Unknown			Astellas
	Tacrolimus			S	Unknown			Astellas
	Azathioprine			S	Unknown	Unk, Unknown Freq.		Not Reported
	Methotrexate			S	Unknown	Unk, Unknown Freq.		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Gold			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15912115	NON-EXPEDITED			US-ABBVIE-18K-163-2484812-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15914265	NON-EXPEDITED			US-ABBVIE-18K-163-2476752-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	15915352	NON-EXPEDITED			US-ABBVIE-18K-163-2607470-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16048932	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018185639		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Arthralgia; Arthropathy; Arthropathy; Contraindicated Product Administered; Dermatitis; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gallbladder Disorder; Gastric Disorder; Groin Pain; Joint Swelling; Miliaria; Miliaria; Off Label Use; Pancreatitis;	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	Unk, Qwk		Unknown
	Celecoxib			S	Unknown	200 Milligram, Q12h		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk, 11:1 Mg		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Unknown
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported

Photosensitivity Reaction; Pruritus Allergic; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Dilaudid	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Citalopram	C	Unknown	10 Mg, 1x/Day	Not Reported
	Citalopram	C		Unk	Not Reported
	Celebrex	C		200 Mg, 2x/Day	Not Reported
	Celebrex	C		Unk	Not Reported
	Lorazepam	C		1 Mg, 1x/ Day (At Bedtime)	Not Reported
	Lorazepam	C		Unk	Not Reported
	Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
	Prednisone	C		Unk	Not Reported
	Pantoloc	C		40 Mg, 2x/Week	Not Reported
	Pantoloc	C	Unknown	40 Mg, 2x/Day	Not Reported
	Pantoloc	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16122586	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2018175541		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram, Unk		Pfizer
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Pfizer
	Enbrel			S	Unknown	25 Mg, Qwk		Pfizer
	Salazopyrin			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Milligram, Qwk		Unknown

Methotrexate Sodium	S	Unknown	20 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Unknown	15 Mg, Weekly	Pfizer
Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	25 Milligram	Not Reported
Orencia	S	Subcutaneous	250 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Gold	S	Subcutaneous	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	300 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	20 Mg, 2x/Day	Not Reported
Plaquenil	S	Oral	200 Milligram, Bid	Not Reported

	Actemra	S	Unknown	Unk	Not Reported
	Arava	C	Oral	10 Milligram	Not Reported
	Bifidobacterium Bifidum	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Loperamide	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	40 Milligram	Not Reported
	Prednisone	C		250 Milligram	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16133266	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-0898			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16189081	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP011205		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Amitriptyline			S	Unknown			Apotex
	Azathioprine			S	Unknown			Apotex
	Cyclosporine			S	Unknown			Apotex
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Apotex
	Leflunomide			S	Unknown			Apotex
	Oxycodone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Medroxyprogesterone			S	Unknown	Unk		Not Reported
	Depo-Provera			S	Unknown			Not Reported
	Etanercept			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Infliximab			S	Unknown	400 Mg, Total		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown	Unk		Not Reported
	Cyclosporine			C	Unknown	Unk		Not Reported
	Depo-Provera			C	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16207344	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019167550			Female	CAN

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

Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S			Not Reported
	Naproxen	C		500 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16234392	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-036882		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Off Label Use; Rash; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Arava	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Simponi	C	Subcutaneous	50 Milligram, Qmo	Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, 2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16722029	EXPEDITED (15-DAY)		DS, OT	CA-CELGENEUS-CAN-20190805428			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Otezla			S	Oral			Celgene
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	16817760	EXPEDITED (15-DAY)			CA-VALIDUS PHARMACEUTICALS LLC-CA-2019VAL000509			Unknown	CAN

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

Depression; Drug Ineffective; Drug Intolerance; Hypersensitivity	Plaquenil /00072603/	S	Unknown	Unk	Not Reported
	Arava	C		Unk	Not Reported
	Buprenorphine	C		Unk	Not Reported
	Xarelto	C		Unk	Not Reported
	Bisoprolol	C	Unknown	Unk	Not Reported
	Lasix /00032602/	C		Unk	Not Reported
	Vitamin D /00107901/	C		Unk	Not Reported
	Vitamin B12 Nos	C		Unk	Not Reported
	Vitamin B6	C		Unk	Not Reported
	Fish Oil	C		Unk	Not Reported
	Calcium	C		Unk	Not Reported
	Magnesium	C		Unk	Not Reported
	Ramipril	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17021208	EXPEDITED (15-DAY)		CA, DE, OT	FR-MYLANLABS-2019M1106907			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby; Patent Ductus Arteriosus; Premature Baby; Premature Separation Of Placenta; Right-To-Left Cardiac Shunt	Esomeprazole			S	Transplacental	Maternal Dose: 20 Mg, Qd		Not Reported
	Plaquenil /00072603/			S	Transplacental	Maternal Dose: 400 Mg Qd		Mylan
	Diffu K			S	Transplacental	1 Dosage Form, Qd		Mylan
	Cortancyl			S	Transplacental	Maternal Dose:1 Df, Qd		Mylan
	Imurel /00001501/			S	Transplacental	150 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17147710	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019205773		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	8 Milligram/Kilogram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17242739	NON-EXPEDITED			NVSC2020US000828		8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Rituximab			S	Unknown	Unk		Not Reported

	Hydroxychloroquine		S	Unknown	Unk	Novartis
	Methotrexate		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17251356	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2020SE00846		28 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis	Inexium			S	Oral			Astrazeneca
	Tardyferon			S	Oral			Not Reported
	Cortancyl			S	Oral			Not Reported
	Levothyrox			S	Oral	100ug/Inhal Daily		Not Reported
	Imurel			S	Oral			Not Reported
	Kardegic			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17278596	EXPEDITED (15-DAY)		DE, HO, OT	US-ASTRAZENECA-2020SE07371		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suspected Suicide	Esomeprazole Magnesium			S	Oral	Unk		Not Reported
	Clindamycin Hcl			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Cyclobenzaprine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17316856	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020032259			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Unknown

Arthritis	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	10 Mg, Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Simponi	C	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17333011	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3253493-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Off Label Use; Pharyngeal Oedema; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Arava			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17370427	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533710			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Naproxen	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17373500	EXPEDITED (15-DAY)		DS	CA-ROCHE-2531906		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Joint Swelling; Limb Discomfort; Mass; Mobility Decreased; Pain; Peripheral Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17373594	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539457		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17373911	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533703			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17374219	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533915			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Occlusive dressing technique			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Vitamin B1 [Thiamine]			S	Unknown			Not Reported
	Aclasta			C	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported

Ascorbic Acid	C	Unknown	Not Reported
Biotin	C	Unknown	Not Reported
Cholecalciferol	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Ferrous Fumarate	C	Unknown	Not Reported
Ferrous Gluconate	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Nortriptyline	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Retinol Palmitate	C	Unknown	Not Reported
Riboflavin	C	Unknown	Not Reported
Thiamine Hydrochloride	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Vitamin A [Retinol]	C	Unknown	Not Reported
Vitamin B3	C	Unknown	Not Reported
Vitamin B6	C	Unknown	Not Reported
Vitamin C [Ascorbic Acid]	C	Unknown	Not Reported
Nasonex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17374397	EXPEDITED (15-DAY)		DE, HO	US-ALVOGEN-2020-ALVOGEN-102684		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Toxicity To	Naproxen			S	Oral			Not Reported

Various Agents	Ibuprofen	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17374779	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023720		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Plaquenil			S		Unk		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Methotrexate			S	Intravenous (not otherwise specified)	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	20 Mg, Qw		Not Reported
	Methotrexate			S		20 Mg Qw		Not Reported
	Actemra			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow (Solution)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17374782	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA025870			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities	Hydroxychloroquine			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Oral			Not Reported
	Celecoxib			S				Not Reported
	Enbrel			S				Not Reported
	Actemra			S				Not Reported

Humira	S	Subcutaneous		Not Reported
Orencia	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S			Not Reported
Prednisone	C	2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17375092	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540680			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17375337	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0655		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17375889	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2537125			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported

Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Anakinra	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17375961	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2537152			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported

	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17376135	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535459			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Fosamax	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17376221	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535980			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17376382	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539454			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17376739	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533781		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377492	NON-EXPEDITED			US-ABBVIE-19K-163-2658597-00			Female	USA

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

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Rituxan		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377497	EXPEDITED (15-DAY)		HO	CN-IPCA LABORATORIES LIMITED-IPC-2020-CN-000399			Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phospholipidosis	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca
	Prednisone			C	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377511	NON-EXPEDITED			US-ABBVIE-19K-163-2660980-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Diarrhoea; Drug Hypersensitivity; Hepatic Function Abnormal; Psoriasis	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Glimepiride			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377526	NON-EXPEDITED			US-ABBVIE-19K-163-2658649-00			Unknown	USA

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

Ineffective; Drug Intolerance	Methotrexate		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Cimzia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377532	NON-EXPEDITED			US-ABBVIE-19K-163-2618887-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377651	NON-EXPEDITED			US-ABBVIE-19K-163-2663000-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377848	NON-EXPEDITED			US-ABBVIE-19K-163-2663033-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Humira			S	Subcutaneous			Not Reported

Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Methotrexate		S	Oral	Not Reported
	Enbrel		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377864	NON-EXPEDITED			US-ABBVIE-19K-163-2663035-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Sinusitis; Diarrhoea; Drug Hypersensitivity; Drug Hypersensitivity; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hcq			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377887	NON-EXPEDITED			US-ABBVIE-19K-163-2662918-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Drug Ineffective; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377912	NON-EXPEDITED			US-ABBVIE-19K-163-2628453-00			Unknown	USA

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

Drug Hypersensitivity; Nausea; Therapeutic Product Effect Decreased; Vomiting	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituxan	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz Xr	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377922	NON-EXPEDITED			US-ABBVIE-19K-163-2666857-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Migraine	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377937	NON-EXPEDITED			US-ABBVIE-19K-163-2665118-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Eruption; Drug Intolerance; Necrosis; Nephrotic Syndrome; Oedema	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Penicillamine			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Arava	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377951	NON-EXPEDITED			US-ABBVIE-19K-163-2636615-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377967	NON-EXPEDITED			US-ABBVIE-19K-163-2665116-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Injection Site Reaction; Pruritus; Rash; Urticaria	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377980	NON-EXPEDITED			US-ABBVIE-19K-163-2665109-00			Unknown	USA

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

Ineffective; Drug Ineffective	Humira	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Methotrexate	C			Not Reported
	Xeljanz Xr	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377984	NON-EXPEDITED			US-ABBVIE-19K-163-2662926-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Eye Disorder	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17377988	NON-EXPEDITED			US-ABBVIE-19K-163-2667995-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378056	NON-EXPEDITED			US-ABBVIE-19K-163-2666891-00			Unknown	USA

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

Ineffective; Drug Ineffective	Methotrexate		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378076	NON-EXPEDITED			US-ABBVIE-19K-163-2666894-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Hand Deformity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Urticaria	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378141	NON-EXPEDITED			US-ABBVIE-19K-163-2666886-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Myalgia; Nausea; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous	12 Years		Not Reported
	Methotrexate			S	Oral	10 Years		Not Reported
	Hydroxychloroquine			S	Unknown	10 Years		Not Reported
	Sulfasalazine			S	Unknown	For 10 Years		Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378142	NON-EXPEDITED			US-ABBVIE-19K-163-2666914-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect	Humira			S	Subcutaneous			Not Reported

Incomplete	Methotrexate		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378152	NON-EXPEDITED			US-ABBVIE-19K-163-2666769-00		54 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Fatigue; Infection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold Injections			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378188	NON-EXPEDITED			US-ABBVIE-19K-163-2666788-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Exposure During Pregnancy; Injection Site Rash	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378200	NON-EXPEDITED			US-ABBVIE-19K-163-2666879-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective;	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral	Prior To May 2018 For		Not Reported

Gastrointestinal Disorder				Two Years	
	Enbrel	S	Unknown		Not Reported
	Rituxan	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378202	NON-EXPEDITED			US-ABBVIE-19K-163-2665120-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378220	NON-EXPEDITED			US-ABBVIE-19K-163-2666656-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378235	NON-EXPEDITED			US-ABBVIE-19K-163-2666632-00			Unknown	USA

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

	Enbrel	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378245	NON-EXPEDITED			US-ABBVIE-19K-163-2666741-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378252	NON-EXPEDITED			US-ABBVIE-19K-163-2668063-00			Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378260	NON-EXPEDITED			US-ABBVIE-19K-163-2666774-00			Unknown	USA

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

Ineffective; Drug Ineffective	Orencia		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378289	NON-EXPEDITED			US-ABBVIE-19K-163-2667013-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Dizziness; Drug Hypersensitivity; Drug Ineffective; Fluid Retention; Headache; Herpes Zoster; Neuropathy Peripheral; Stomatitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378291	NON-EXPEDITED			US-ABBVIE-19K-163-2671146-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Colchicine			C				Not Reported
	Motrin			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378292	NON-EXPEDITED			US-ABBVIE-19K-163-2643787-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378310	NON-EXPEDITED			US-ABBVIE-19K-163-2671152-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378330	NON-EXPEDITED			US-ABBVIE-19K-163-2666975-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378352	NON-EXPEDITED			US-ABBVIE-19K-163-2666927-00			Unknown	USA

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

Cardiac Failure; Drug Ineffective	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378373	NON-EXPEDITED			US-ABBVIE-19K-163-2666719-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Remicade			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378379	NON-EXPEDITED			US-ABBVIE-19K-163-2666659-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Malaise; Myalgia; Nausea; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other	Usp		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378384	NON-EXPEDITED			US-ABBVIE-19K-163-2666660-00			Unknown	USA

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

Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Drug Ineffective; Psoriasis	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378410	NON-EXPEDITED			US-ABBVIE-19K-163-2670791-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Drug Ineffective; Nausea; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378418	NON-EXPEDITED			US-ABBVIE-19K-163-2666952-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Memory Impairment	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378441	NON-EXPEDITED			US-ABBVIE-19K-163-2670727-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378464	NON-EXPEDITED			US-ABBVIE-19K-163-2670911-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi Aria			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378472	NON-EXPEDITED			US-ABBVIE-19K-163-2670898-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mobic			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378475	NON-EXPEDITED			US-ABBVIE-19K-163-2667035-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Drug Intolerance; Nausea; Rheumatoid Arthritis;	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

Therapeutic Product Effect Decreased	Enbrel		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378501	NON-EXPEDITED			US-ABBVIE-19K-163-2667990-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378513	NON-EXPEDITED			US-ABBVIE-19K-163-2671178-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cognitive Disorder; Contusion; Depression; Fatigue; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378529	NON-EXPEDITED			US-ABBVIE-19K-163-2646176-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378540	NON-EXPEDITED			US-ABBVIE-19K-163-2670962-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378545	NON-EXPEDITED			US-ABBVIE-19K-163-2667056-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378565	NON-EXPEDITED			US-ABBVIE-19K-163-2647284-00		35 YR	Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378572	NON-EXPEDITED			US-ABBVIE-19K-163-2667992-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actamol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378573	NON-EXPEDITED			US-ABBVIE-19K-163-2667989-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Injection Site Rash; Injection Site Rash; Pain; Pain; Swelling; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378578	NON-EXPEDITED			US-ABBVIE-19K-163-2667062-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Primary Biliary Cholangitis; Therapeutic Product Effect Incomplete; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378602	NON-EXPEDITED			US-ABBVIE-19K-163-2671180-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378612	NON-EXPEDITED			US-ABBVIE-19K-163-2647659-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378635	NON-EXPEDITED			US-ABBVIE-19K-163-2671247-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Increased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378637	NON-EXPEDITED			US-ABBVIE-19K-163-2653591-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Infection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378668	NON-EXPEDITED			US-ABBVIE-19K-163-2653576-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378671	NON-EXPEDITED			US-ABBVIE-19K-163-2676244-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Infection; Therapeutic Product Effect Incomplete; Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Other			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cefuroxime			C				Not Reported
	Flagyl			C				Not Reported
	Topiramate			C				Not Reported
	Percocet			C				Not Reported
	Darvocet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378673	NON-EXPEDITED			US-ABBVIE-19K-163-2653480-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Doxycyclin			S	Unknown			Not Reported
	Macrobid			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Triamterene			S	Unknown			Not Reported
	Proair			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378678	NON-EXPEDITED			US-ABBVIE-19K-163-2671251-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Metotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378683	NON-EXPEDITED			US-ABBVIE-19K-163-2673925-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Rash	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported

	Methotrexate	C	Oral	Not Reported
	Hydroxychloroquine	C	Oral	Not Reported
	Hydroxychloroquine	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378687	NON-EXPEDITED			US-ABBVIE-19K-163-2654903-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378701	NON-EXPEDITED			US-ABBVIE-19K-163-2654855-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Headache; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378704	NON-EXPEDITED			US-ABBVIE-19K-163-2654915-00			Unknown	USA

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

Product Effect Decreased	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378753	NON-EXPEDITED			US-ABBVIE-19K-163-2657336-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear; Liver Function Test Abnormal; Malaise; Skin Toxicity	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378764	NON-EXPEDITED			US-ABBVIE-19K-163-2654916-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378772	NON-EXPEDITED			US-ABBVIE-19K-163-2657293-00			Unknown	USA

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

	Imuran	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378776	NON-EXPEDITED			US-ABBVIE-19K-163-2657324-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378833	NON-EXPEDITED			US-ABBVIE-19K-163-2657214-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gastrointestinal Disorder; Injection Site Reaction; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378852	NON-EXPEDITED			US-ABBVIE-19K-163-2653583-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Cellcept			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Hydroxychloroquine			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378864	NON-EXPEDITED			US-ABBVIE-19K-163-2653595-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Eruption; Drug Ineffective; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378872	NON-EXPEDITED			US-ABBVIE-19K-163-2672101-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378876	NON-EXPEDITED			US-ABBVIE-19K-163-2672102-00			Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378899	NON-EXPEDITED			US-ABBVIE-19K-163-2657386-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378900	NON-EXPEDITED			US-ABBVIE-19K-163-2656772-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378907	NON-EXPEDITED			US-ABBVIE-19K-163-2659092-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378927	NON-EXPEDITED			US-ABBVIE-19K-163-2656775-00		71 YR	Unknown	USA

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

Arthralgia; General Symptom; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira		S	Subcutaneous	Not Reported
	Humira		S		Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S		Not Reported
	Enbrel		S	Unknown	Not Reported
	Enbrel		S		Not Reported
	Plaquenil		S	Unknown	Not Reported
	Plaquenil		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378938	NON-EXPEDITED			US-ABBVIE-19K-163-2657344-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Vectra (Valdecoxib)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378941	NON-EXPEDITED			US-ABBVIE-19K-163-2674610-00			Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378947	NON-EXPEDITED			US-ABBVIE-19K-163-2659106-00			Unknown	USA

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

Injection Site Rash; Nausea; Therapeutic Product Effect Decreased	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Simponi Aria	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Azathioprin	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378952	NON-EXPEDITED			US-ABBVIE-19K-163-2674641-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Liver Function Test Increased; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378953	NON-EXPEDITED			US-ABBVIE-19K-163-2655231-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378955	NON-EXPEDITED			US-ABBVIE-19K-163-2672763-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Psoriasis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378956	NON-EXPEDITED			US-ABBVIE-19K-163-2657353-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378968	NON-EXPEDITED			US-ABBVIE-19K-163-2655234-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Azulfidine			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378969	NON-EXPEDITED			US-ABBVIE-19K-163-2680610-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Xeljanz Xr			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378977	NON-EXPEDITED			US-ABBVIE-19K-163-2655240-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378978	NON-EXPEDITED			US-ABBVIE-19K-163-2672766-00		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Chills; Diverticulitis; Ear Congestion; Neuritis; Pain; Rash; Sinus Congestion	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflumide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Calcium	C	Unknown	Not Reported
	Vitamin D	C	Unknown	Not Reported
	Fish Oil	C	Unknown	Not Reported
	Vitamin C	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17378980	NON-EXPEDITED			US-ABBVIE-19K-163-2655230-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379003	NON-EXPEDITED			US-ABBVIE-19K-163-2658652-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379004	NON-EXPEDITED			US-ABBVIE-19K-163-2674609-00			Unknown	USA

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

Ineffective; Drug Ineffective	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379006	NON-EXPEDITED			US-ABBVIE-19K-163-2672139-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Bone Pain; Drug Ineffective; Drug Ineffective; Fatigue; Injection Site Reaction; Myalgia; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Other			Not Reported
	Cimzia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379009	NON-EXPEDITED			US-ABBVIE-19K-163-2680576-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379013	NON-EXPEDITED			US-ABBVIE-19K-163-2656935-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Actemra		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379023	NON-EXPEDITED			US-ABBVIE-19K-163-2678299-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Injection Site Reaction; Pain	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379024	NON-EXPEDITED			US-ABBVIE-19K-163-2655039-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379028	NON-EXPEDITED			US-ABBVIE-19K-163-2656934-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Headache	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azulfidine			S	Unknown			Not Reported

	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379039	NON-EXPEDITED			US-ABBVIE-19K-163-2658600-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379050	NON-EXPEDITED			US-ABBVIE-19K-163-2672549-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379051	NON-EXPEDITED			US-ABBVIE-19K-163-2656936-00			Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379054	NON-EXPEDITED			US-ABBVIE-19K-163-2680578-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz Xr			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379061	NON-EXPEDITED			US-ABBVIE-19K-163-2658650-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379066	NON-EXPEDITED		OT	US-ABBVIE-19K-163-2675710-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Treatment Failure; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Other			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379091	NON-EXPEDITED			US-ABBVIE-19K-163-2680465-00			Unknown	USA

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

Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Epistaxis; Paraesthesia	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379114	NON-EXPEDITED			US-ABBVIE-19K-163-2675964-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Blood Glucose Increased; Eye Disorder; Migraine; Nausea; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379119	NON-EXPEDITED			US-ABBVIE-19K-163-2680466-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Sulfasalazine		S	Unknown	Not Reported
	Simponi		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379134	NON-EXPEDITED			US-ABBVIE-19K-163-2662836-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Avara			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379154	NON-EXPEDITED			US-ABBVIE-19K-163-2680463-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Nausea; Pigmentation Disorder; Vomiting	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379158	NON-EXPEDITED			US-ABBVIE-19K-163-2680575-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz Xr			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379180	NON-EXPEDITED			US-ABBVIE-19K-163-2662835-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Exposure During Pregnancy; Rash	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379195	NON-EXPEDITED			US-ABBVIE-19K-163-2655279-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379198	NON-EXPEDITED			US-ABBVIE-19K-163-2675962-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Dmards (Disease Modifying Antirheumatic Drugs)			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379207	NON-EXPEDITED			US-ABBVIE-19K-163-2655292-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Injection Site Pruritus; Liver Function Test Increased	Humira			S	Subcutaneous	Treatment Length 2 Years		Not Reported
	Methotrexate			S	Unknown	Treatment Length 4 Years		Not Reported
	Actemra			S	Unknown	Treatment Length 3 Years		Not Reported
	Plaquenil			S	Unknown	Treatment Length 3 Years		Not Reported
	Prednisone			C		Continuing		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379212	NON-EXPEDITED			US-ABBVIE-19K-163-2662839-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Risk Factor; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379229	NON-EXPEDITED			US-ABBVIE-19K-163-2678304-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Rash; Swelling	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379230	NON-EXPEDITED			US-ABBVIE-19K-163-2662844-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379241	NON-EXPEDITED			US-ABBVIE-19K-163-2685718-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Therapeutic Product Effect Decreased; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379259	NON-EXPEDITED			US-ABBVIE-19K-163-2680577-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379260	NON-EXPEDITED			US-ABBVIE-19K-163-2662888-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379263	NON-EXPEDITED			US-ABBVIE-19K-163-2662915-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Muscular Weakness; Myalgia	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379274	NON-EXPEDITED			US-ABBVIE-19K-163-2672164-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Pain	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hcq			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379275	NON-EXPEDITED			US-ABBVIE-19K-163-2675877-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379287	NON-EXPEDITED			US-ABBVIE-19K-163-2685876-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Hypersensitivity; Latent Tuberculosis; Nightmare; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379303	NON-EXPEDITED			US-ABBVIE-19K-163-2660549-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379325	NON-EXPEDITED			US-ABBVIE-19K-163-2660734-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379334	NON-EXPEDITED			US-ABBVIE-19K-163-2680399-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379340	NON-EXPEDITED			US-ABBVIE-19K-163-2685826-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Zofran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379348	NON-EXPEDITED			US-ABBVIE-19K-163-2676033-00			Unknown	USA

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

Drug Ineffective; Drug Ineffective; Rheumatoid Arthritis; Synovitis	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379358	NON-EXPEDITED			US-ABBVIE-19K-163-2660552-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Liver Function Test Increased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379374	NON-EXPEDITED			US-ABBVIE-19K-163-2673857-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Hepatic Function Abnormal	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379444	NON-EXPEDITED			US-ABBVIE-19K-163-2685872-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379448	NON-EXPEDITED			US-ABBVIE-19K-163-2686454-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379475	NON-EXPEDITED			US-ABBVIE-19K-163-2686463-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contraindicated Product Administered; Rash; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379497	NON-EXPEDITED			US-ABBVIE-19K-163-2662758-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure; Vaginal Haemorrhage	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379532	NON-EXPEDITED			US-ABBVIE-19K-163-2658790-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379547	NON-EXPEDITED			US-ABBVIE-19K-163-2690386-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Bupropion			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Penicillin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfa			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379562	NON-EXPEDITED			US-ABBVIE-19K-163-2687499-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Malaise; Pain	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Mobic			S	Unknown			Not Reported

	Diclofenac			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379563	NON-EXPEDITED			US-ABBVIE-19K-163-2682481-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Ineffective; Osteoporosis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379568	NON-EXPEDITED			US-ABBVIE-19K-163-2690387-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Drug Reaction; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379598	NON-EXPEDITED			US-ABBVIE-19K-163-2683928-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379608	NON-EXPEDITED			US-ABBVIE-19K-163-2687505-00			Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379610	NON-EXPEDITED			US-ABBVIE-19K-163-2690696-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Diarrhoea; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Injection Site Reaction; Oedema Peripheral; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379613	NON-EXPEDITED			US-ABBVIE-19K-163-2687654-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Oral Pain; Urticaria; Urticaria	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379622	NON-EXPEDITED			US-ABBVIE-19K-163-2687656-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Intolerance; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379626	NON-EXPEDITED			US-ABBVIE-19K-163-2690704-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379628	NON-EXPEDITED			US-ABBVIE-19K-163-2690481-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Drug	Humira			S	Subcutaneous			Not Reported

Hypersensitivity; Drug Ineffective	Xeljanz Xr		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379634	NON-EXPEDITED			US-ABBVIE-19K-163-2683932-00			Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379742	NON-EXPEDITED			US-ABBVIE-19K-163-2699997-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Humira			S	Subcutaneous			Not Reported
	Insulin			S	Unknown			Not Reported
	Lantus			S	Unknown			Not Reported
	Byetta			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379804	NON-EXPEDITED			US-ABBVIE-19K-163-2692420-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Immunodeficiency; Infection; Malaise; Skin Lesion; Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379843	NON-EXPEDITED			US-ABBVIE-19K-163-2692238-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Headache; Nausea	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Matrix			C				Not Reported
	Tramadol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379884	NON-EXPEDITED			US-ABBVIE-19K-163-2694201-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Gastrointestinal Disorder; Nausea	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17379940	NON-EXPEDITED			US-ABBVIE-19K-163-2700215-00			Unknown	USA

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

Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Methotrexate	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380132	NON-EXPEDITED			US-ABBVIE-19K-163-2720959-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Hypersensitivity; Injection Site Reaction; Injection Site Reaction; Pain	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380314	NON-EXPEDITED			US-ABBVIE-19K-163-2684071-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380337	NON-EXPEDITED			US-ABBVIE-19K-163-2666928-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Metotrexate			S	Unknown			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380339	NON-EXPEDITED			US-ABBVIE-19K-163-2685846-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380341	NON-EXPEDITED			US-ABBVIE-19K-163-2692448-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Injection Site Reaction	Humira			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380465	NON-EXPEDITED			US-ABBVIE-19K-163-2700189-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17380607	NON-EXPEDITED			US-ABBVIE-19K-163-2665125-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Liver Function Test Increased; Neutrophil Count Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17381346	NON-EXPEDITED			US-ABBVIE-19K-163-2787760-00			Unknown	USA

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

Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Fatigue; Myalgia; Pain	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Otezla		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17382125	NON-EXPEDITED			US-ABBVIE-19K-163-2828069-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Drug Intolerance; Drug Intolerance; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17383574	NON-EXPEDITED			US-ABBVIE-19K-163-2988548-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Mobic			S	Unknown			Not Reported
	Naltrexone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384445	NON-EXPEDITED			US-ABBVIE-19K-163-2884124-00			Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384724	NON-EXPEDITED			US-ABBVIE-19P-163-2655187-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Injection Site Reaction; Therapy Non-Responder; Tremor	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384744	NON-EXPEDITED		OT	US-ABBVIE-19K-163-2899418-00		54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Myalgia; Swelling; Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Livalo			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384758	NON-EXPEDITED			US-ABBVIE-19S-163-2678318-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Injection Site Reaction; Injection Site Reaction	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384792	NON-EXPEDITED			US-ABBVIE-19S-163-2690751-00			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Obstructive Pulmonary Disease; Drug Ineffective; Drug Ineffective; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384797	NON-EXPEDITED			US-ABBVIE-19S-163-2690760-00			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17384888	NON-EXPEDITED			US-ABBVIE-19K-308-2957867-00			Unknown	USA

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

Drug Hypersensitivity; Exercise Tolerance Decreased; Oropharyngeal Pain; Sinus Disorder; Throat Irritation	Humira	S	Subcutaneous		Not Reported
	Xeljanz Xr	S	Unknown		Not Reported
	Rosuvastatin	S	Unknown		Not Reported
	Ursodiol	S	Unknown	300 Mg	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Amlodipine	S	Unknown		Not Reported
	Lifitegrast	C		590 (Xiidra)	Not Reported
	Vitamin C	C			Not Reported
	Vitamin D Nos	C			Not Reported
	Flaxseed Oil	C			Not Reported
	Omega 3	C			Not Reported
	Turmeric	C			Not Reported
	Biotin	C			Not Reported
	Calcium + Magnesium + Zink	C			Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17385384	NON-EXPEDITED			US-ABBVIE-19K-163-2905899-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Barrett'S Oesophagus; Cough; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Gastric Disorder; Nausea; Nightmare; Peripheral Swelling; Pruritus; Skin Papilloma; Trigger Finger; Urinary Tract Infection	Humira			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Other			Not Reported
	Arava			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Azulfidine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Mobic			C	Oral			Not Reported

Celebrex	C				Not Reported
Celebrex	C				Not Reported
Ibuprofen	C	Oral			Not Reported
Sulfasalazine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17386476	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020047495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Cosentyx			S	Unknown	150 Mg, Monthly		Not Reported
	Humira			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	10 Mg, Unk		Not Reported
	Plaquenil S			S	Unknown	200 Mg, 2x/Day		Not Reported
	Prednisone			S	Unknown			Not Reported
	Cymbalta			C	Oral	60 Mg, 1x/Day		Not Reported
	Esomeprazole Magnesium/Naproxen Sodium			C	Oral			Not Reported
	Tylenol [Paracetamol]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17386479	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020047497			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Pain; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17386806	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-20200111049		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Otezla			S	Oral	120 Milligram		Celgene
	Otezla			S				Celgene
	Otezla			S				Celgene
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ibuprofen			S	Oral	600 Milligram		Not Reported
	Infliximab			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Tocilizumab			S	Unknown	360 Milligram		Not Reported
	Tocilizumab			S	Unknown	680 Milligram		Not Reported
	Sulfasalazine			S	Endocervical			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Rituxan	S	Intravenous drip	2000 Milligram		Not Reported
Remicade	S	Intravenous drip			Not Reported
Benadryl	C	Unknown			Not Reported
Mogadon	C	Oral			Not Reported
Colchicine	C	Unknown			Not Reported
Nitrazepam	C	Oral	5 Milligram		Not Reported
Dexilant	C	Oral			Not Reported
Febuxostat	C	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Gravol	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported
Uloric	C	Oral			Not Reported
Oxycodone	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17386824	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-003377		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal	Topicort			S	Unknown	Not Specified		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Oral	Not Specified		Not Reported
	Diclofenac Sodium			S	Unknown	Not Specified		Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported

Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Unknown	Not Specified	Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Atasol	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17388975	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535957			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2020	17388990	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536717			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	11666289	EXPEDITED (15-DAY)		OT	CA-ROCHE-1648220			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 577.0 Nos		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Duration:577.0		Not Reported
	Methotrexate			S	Unknown	Duration: 577.0		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 577.0 Nos		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Therapy Duration: 577.0		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous	Duration: 577.0		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Duration: 577.0		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown	Duration: 577.0		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Cortisone	C	Oral	Not Reported
	Desoximetasone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	12082828	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712228			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)	4-8mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	Adequate Trial Of 3months In 2010		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 195 Days Form Of Admin Text: Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Therapy Duration: 6 Years		Not Reported
	Methotrexate			S	Intramuscular	Therapy Duration: 6 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration: 6 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

Apo-Hydroxyquine	S	Oral			Not Reported
Methotrexate Sodium	S	Oral			Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Leflunomide	S	Oral			Not Reported
Acetylsalicylic Acid	C	Unknown			Not Reported
Asa	C	Unknown			Not Reported
Lantus	C	Subcutaneous	Solution		Not Reported
Lozide [Indapamide]	C				Not Reported
Prednisone	C				Not Reported
Ramipril	C				Not Reported
Ergocalciferol	C				Not Reported
Vitamin D3	C				Not Reported
Xeljanz	C	Oral			Not Reported
Calcium	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	12301325	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2014360295		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Carpal Tunnel Syndrome; Diarrhoea; Drug Ineffective; Fibromyalgia; Hepatic Enzyme Increased; Joint Swelling; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Rheumatoid Arthritis; Spinal Stenosis	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S		Between 17.5 Mg And 25mg, Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Oral	2 G, Daily		Pfizer
	Humira			S	Unknown	Unk		Not Reported
	Humira			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Arava			S		20 Mg, 1x/Day		Not Reported
	Arava			S				Not Reported
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Plaquenil			S		Unk		Not Reported

Plaquenil	S	Unknown	300 Mg, Weekly	Not Reported
Tramacet	S		Unk	Not Reported
Aclasta	S	Intravenous (not otherwise specified)	Unk, Single	Not Reported
Tramadol/Acetaminophen	S	Oral	Unk	Not Reported
Nortriptylin	C		20 Mg, 1x/Day At Bedtime (2 Tablets Per Day)	Not Reported
Nortriptylin	C			Not Reported
Metformin	C		5 Milligram, Qd	Not Reported
Metformin	C		500 Milligram, Bid	Not Reported
Lorazepam	C		1 Mg, 1x/Day Nightly	Not Reported
Vagifem	C		Unk	Not Reported
Lyrica	C	Oral	150 Mg, 2x/Day	Not Reported
Premarin	C		0.625 Mg, Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Calcium	C		Unk	Not Reported
Depomedrol	C	Subcutaneous	40 Mg, Monthly	Not Reported
Depomedrol	C	Subcutaneous	Unk Unk, Qmo	Not Reported
Depomedrol	C			Not Reported
Tylenol Arthritis	C		Unk	Not Reported
Actonel Dr	C		35 Mg, Weekly	Not Reported
Ergocalciferol	C		Unk	Not Reported
Methylprednisolone Acetate	C	Intramuscular	40 Mg, 1 Every 1 Month	Not Reported
Methylprednisolone Acetate	C	Subcutaneous	Unk, Monthly	Not Reported
Methylprednisolone Acetate	C			Not Reported
Nortriptyline Hydrochloride	C		20 Mg, Qd	Not Reported
Nortriptyline	C		Unk (Tablet And Capsule)	Not Reported
Nortriptyline	C			Not Reported
Risedronate Sodium	C	Unknown	35 Milligram, Qwk	Not Reported
Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	12678829	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016108462			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Neoral			S	Oral	20 Milligram		Not Reported
	Plaquenil			S	Oral	20 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	13119773	EXPEDITED (15-DAY)		OT	CA-ROCHE-1880386		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported

	Hydroxychloroquine		S	Oral	Not Reported
	Naprosyn [Naproxen]		C	Unknown	Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	13271760	EXPEDITED (15-DAY)		OT	CA-ROCHE-1897736		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contraindicated Product Administered; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	Therapy Duration 365 Days		Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 3.0 Month(S)		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 4.0 Year(S)		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration: 4.0 Month(S)		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported

	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	13602521	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-047783		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Synovitis; Throat Tightness	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	14235038	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021663		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional	Hydroxychloroquine			S	Unknown	Unk, Qd		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk (Cyclical)		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	1 Df, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex

Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Leflunomide	S	Oral	20 Mg, 1 Every 1 Hour	Apotex
	Leflunomide	S	Oral	20 Mg, Unk (Cyclical)	Apotex
	Risedronate	S	Oral	35 Mg, Q.Wk.	Apotex
	Humira	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	35 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actonel	S	Unknown	35 Mg, Q.Wk.	Not Reported
	Plaquenil /00072602/	S	Oral	300 Mg, Qd	Not Reported
	Anakinra	S	Subcutaneous	100 Mg, Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Risedronic Acid	S	Oral	35 Mg, Q.Wk.	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk (Cyclical)	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	10 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Risedronate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	14246628	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006309		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Acetaminophen			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Acetaminophen			S	Unknown			Apotex
	Apo-Prednisone			S	Unknown	7.5 Mg, Unk		Apotex
	Hydromorphone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	14549382	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006552		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Muscle Spasms; Pain; Pain In Jaw; Rheumatoid Arthritis	Amitriptyline			S	Unknown	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	14845152	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1364		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	Qwk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Q2wk		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Q2wk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Aleve	C	Unknown	Not Reported
	Bupropion	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15389282	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2667		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Incomplete; Transplant Dysfunction; Transplant Rejection	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rapamune			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Neoral	S	Unknown	Not Reported
	Prograf	S	Unknown	Not Reported
	Prograf	S	Oral	Not Reported
	Prograf	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Imuran	C	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15393834	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184304		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Actonel		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15436912	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189344		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15439303	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189946		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported

Decreased	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Asa	C	Unknown	Not Reported
	Clonazepam	C	Oral	Not Reported
	Desipramine	C	Unknown	Not Reported
	Gabapentin	C	Oral	Not Reported
	Nitroglycerin	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15454775	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-2785		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Bactrim			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15679007	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574090-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C				Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C				Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15696246	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015057052		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased;	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Pfizer
	Xeljanz			S	Oral	5 Mg, Twice Daily		Pfizer
	Xeljanz			S	Oral	10 Mg, Twice Daily		Pfizer
	Xeljanz			S	Oral	5 Milliliter, Bid		Pfizer
	Xeljanz			S	Oral	10 Milliliter, Bid		Pfizer

Therapeutic Product Effect Incomplete	Xeljanz	S	Oral	Unk, Bid	Pfizer
	Xeljanz	S	Oral	10 Milliliter	Pfizer
	Xeljanz	S	Oral	5 Milliliter	Pfizer
	Celebrex	S	Oral	Unk	Pfizer
	Celebrex	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	15 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	20 Milligram	Pfizer
	Methotrexate Sodium	S	Unknown	200 Milligram, Qwk	Pfizer
	Vioxx	S	Oral	Unk	Not Reported
	Vioxx	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported

	Wellbutrin	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15749108	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3822		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Foot Deformity; Hand Deformity; Headache; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Orencia	S	Unknown		Not Reported
Plaquenil	S	Unknown	200mg:1 And A Half Pill	Not Reported
Plaquenil	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Cyclical, On Day 0 And Day 15	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Anakinra	S	Subcutaneous		Not Reported
Anakinra	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Actonel	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Oral	Cyclic	Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Risedronate	S	Unknown		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	15851869	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2634031-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16033390	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019168			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Methotrexate			S	Unknown			Barr
	Rosuvastatin Calcium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported
	Cephalexin			C	Unknown	2000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16214358	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1183			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16302392	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076872		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy; Drug Ineffective; Off Label Use; Pain In Extremity; Peripheral Swelling; Psoriasis	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Remicade			S	Unknown	Unk		Not Reported

	Sulfasalazine			S	Unknown					Not Reported
	Methotrexate			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16481798	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1203		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Medication Error; Off Label Use; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Every 2 Week		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Subcutaneous			Not Reported

Sodium Aurothiomalate	S	Intramuscular	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Actemra	S	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Bifidobacterium Bifidum	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Simponi	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16535717	EXPEDITED (15-DAY)		OT	CA-ROCHE-2346125			Female	CAN

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

Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Folic Acid	S	Unknown	Not Reported
	Apo-Folic Acid	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16820452	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Fatigue; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mammoplasty; Mitral Valve Disease; Off Label Use; Pneumonia; Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Bactrim			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16901988	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2956672-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Humira			S	Subcutaneous			Not Reported
	Tenoxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Bromocriptine			S	Unknown			Not Reported

	Colchicine	S	Unknown	Not Reported
	Ustekinumab	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Pamidronate Disodium	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Doxycycline Hyclate	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Dilaudid	S	Unknown	Not Reported
	Mercaptopurine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	16942141	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1098880		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Iron Deficiency; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Mylan
	Humira			S	Unknown	40 Milligram		Mylan
	Methotrexate			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17072593	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1140303		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Ciclosporin			S	Unknown			Ivax

Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Ciclosporin	S	Oral	Ivax
	Ciclosporin	S	Oral	Ivax
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Imuran	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported

	Orencia	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17164952	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019538925		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	8 Milligram/Kilogram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17388029	EXPEDITED (15-DAY)		HO	CA-ROCHE-2534191			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immunoglobulins [Immunoglobulins Nos]			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17388411	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540683			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Actemra			S	Unknown			Not Reported

Intolerance; Hepatic Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17388482	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537431		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389020	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020050435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Nausea; Neuropathy Peripheral	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Arava			S		20 Mg, 1x/Day		Not Reported

	Hydroxychloroquine Sulfate	S	200 Mg, 1 Every 12 Hours	Not Reported
	Hydroxychloroquine Sulfate	S	200 Mg, 1 Every 12 Hours	Not Reported
	Lyrica	C	Unk	Not Reported
	Meloxicam	C	Unk	Not Reported
	Xeljanz	C	5 Mg, Unk (Every 12 Hours)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389033	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020052260			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1x/Day		Not Reported
	Humira			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389049	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020050421			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Interstitial Lung Disease; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	1 G, 2x/Day		Pfizer
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2x/Day		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	15 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389191	EXPEDITED (15-DAY)		DS	CA-ROCHE-2540903			Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389209	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537446			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389402	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536025		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Respiratory Tract Infection Viral; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389519	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536665		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid	Actemra			S	Unknown			Not Reported

Arthritis; Therapeutic Product Effect Incomplete	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17389826	EXPEDITED (15-DAY)		OT	NVSC2020CA030586			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Hypersensitivity; Impaired Work Ability; Pain; Rheumatoid Arthritis; Swelling; Vomiting	Methotrexate			S	Unknown	Unk		Novartis
	Ibuprofen			S	Unknown	Unk		Not Reported
	Codeine Phosphate			S	Unknown	Unk		Not Reported
	Crestor			S	Unknown	20 Mg, Qd		Not Reported
	Tylenol			S	Unknown	282 Ot		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390361	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2020-003369		44 YR	Female	CAN

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

Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac	S	Ophthalmic	Bausch And Lomb
	Topicort	S	Cutaneous	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Alendronate Sodium	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride/Pseud Oephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Atasol	C		Not Reported
	Salazopyrin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390484	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535796			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown	84.0 Days		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	4.0 Years		Not Reported
	Leflunomide			S	Oral	4.0 Years		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	730.0		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390675	EXPEDITED (15-DAY)		HO, OT	ALC2020CA001016			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Phenylephrine Hydrochloride Injection Usp			S	Unknown	Not Specified		Alcon
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Ot (1 Every 1 Month)		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20.0 Mg		Not Reported
	Benzalkonium Chloride			S	Unknown	Unk		Not Reported
	Benzalkonium Chloride;Diphenhydramine Hydrochloride;Phenylephrine Hydr			S	Unknown			Not Reported
	Benzalkonium Chloride;Diphenhydramine Hydrochloride;Phenylephrine Hydr			S	Unknown	Unk		Not Reported
	Boric Acid			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Diphenhydramine Hydrochloride			S	Unknown			Not Reported
	Disodium Edetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50.0 Mg, Ot (1 Every 1 Weeks)		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Mg Cyclical		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200.0 Mg (2 Every 1 Days)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	15.0 Mg 1 Every 1 Weeks		Not Reported

Methotrexate	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Rho D Immune Globulin	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Sodium Borate	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Tofacitinib Citrate	S	Unknown	5.0 Mg 2 Every 1 Days	Not Reported
Tofacitinib Citrate	S	Unknown	10.0 Unk 2 Every 1 Days	Not Reported
Tofacitinib Citrate	S	Unknown	5.0 G 2 Every 1 Week	Not Reported
Tofacitinib Citrate	S	Subcutaneous	5.0 Unk 2 Every 1 Days	Not Reported
Xeljanz	C	Oral	5.0 Mg 2 Every 1 Days	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Ibuprofen	C	Oral	400.0 Mg	Not Reported
Celebrex	C	Oral	400.0 Mg	Not Reported
Lipitor	C	Oral	10.0 Mg, Ot 1 Every 1 Days	Not Reported
Lipitor	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390768	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535761		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty;	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Musculoskeletal Disorder; Therapeutic Product Effect Decreased	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Methotrexate		C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390821	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0675		29 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Inflammation; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; X-Ray Abnormal	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390834	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0681		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Glucose Increased; C-Reactive Protein Increased; Chest Discomfort; Dizziness; Dyspnoea; Gastrointestinal Disorder; Influenza; Joint Swelling; Lung Disorder; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Neck Pain; Pain In Extremity;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Unknown			Not Reported

Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Sarcoidosis; Sensory Loss; Therapeutic Response Decreased; Tuberculosis; Urinary Tract Infection; Vision Blurred; White Blood Cells Urine Positive	Azathioprine	C	Unknown	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Glyburide	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Methylprednisolone	C	Unknown	Not Reported
	Pariet	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Trajenta	C	Unknown	Not Reported
	Vitamin B6	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390927	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540924			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Enbrel		S	Subcutaneous	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17390978	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535637		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rosuvastatin Calcium			S	Oral			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391199	EXPEDITED (15-DAY)		DE, HO, LT	CA-ROCHE-2537139			Male	CAN

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

Apparent Death; Deep Vein Thrombosis; Diverticulitis; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris	S	Unknown	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391235	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536677		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Anakinra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 5.0 Years	Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 9.0 Years	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 15.0 Years	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Adalimumab	C	Unknown	Therapy Duration: 9.0 Years	Not Reported
	Prednisone	C	Unknown	Therapy Duration: 9.0 Years	Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391683	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536704			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity;	Actemra			S	Subcutaneous			Not Reported

Drug Ineffective; Drug Intolerance; Hypersensitivity; Rash	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Acetylsalicylic Acid	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Gabapentin	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391712	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538305		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatitis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

	Sulfasalazine	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391716	EXPEDITED (15-DAY)		OT	NVSC2020DE026206			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Small For Dates Baby	Prednisolone			S	Transplacental	Mother Dose:5 Mg, Qd (Initially 5 Mg/D Until Gw 6+2, Then Discontinued. From Gw 23+3 Until Delivery		Novartis
	Quensyl			S	Transplacental	Mother Dose: 200 Mg, Qd		Not Reported
	Folsaeure			C	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391789	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538050		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rosuvastatin			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17391992	EXPEDITED (15-DAY)		HO	CA-ROCHE-2533842			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gamastan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392075	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536228		43 YR	Female	CAN

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

Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392107	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541650		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	577.0		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown	577.0		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral	577.0		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	577.0		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	577.0		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	577.0		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	577.0		Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	577.0		Not Reported
	Remicade	S	Unknown			Not Reported
	Simponi	S	Unknown			Not Reported
	Simponi	S	Subcutaneous	577.0		Not Reported
	Desoximetasone	C	Oral			Not Reported
	Desoximetasone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392509	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539797		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatitis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392519	EXPEDITED (15-DAY)		DS	CA-ROCHE-2540672		46 YR	Female	CAN

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

Abdominal Discomfort; Disability; Drug Ineffective; Headache; Malaise	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392615	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536712		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17392847	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542897			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Leflunomide			C	Oral			Not Reported
	Meloxicam			C				Not Reported
	Methotrexate			C				Not Reported
	Synthroid			C				Not Reported
	Tylenol			C				Not Reported
	Codeine			C				Not Reported
	Phosphoric Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17393269	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540678		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Methotrexate		C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Feb-2020	17444146	DIRECT	Y				46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Palpitations	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	13277559	EXPEDITED (15-DAY)		HO, OT	CA-BAXTER-2017BAX008638		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb Fracture	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	Dosage Form Not Specified		Baxter
	Arava			S	Oral	Dosage Form: Tablet		Not Reported
	Cimzia			S	Subcutaneous	Dosage Form Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown	Dosage Form Not Specified		Not Reported
	Plaquenil			S	Oral	Dosage Form: Tablet		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form Powder For Solution Intravenous		Not Reported

	Simponi		S	Subcutaneous	Dosage Form Solution Subcutaneous	Not Reported
	Methotrexate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	15934147	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656830-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methyl Salicylate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392885	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538062			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Hepatic Enzyme Increased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Oxycodone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392930	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542449		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392932	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542453		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392959	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542450		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported

Apo-Leflunomide	S	Oral	Not Reported
Ciclosporin	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Neoral	S	Subcutaneous	Not Reported
Xeljanz Xr	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392964	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542472		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Endocervical			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported

Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Neoral	S	Unknown	Not Reported
Neoral	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17392968	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540896			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393039	EXPEDITED (15-DAY)		HO	CA-ROCHE-2535807		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393055	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542476		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393141	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535785		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sirukumab			S	Unknown			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Ustekinumab	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393173	EXPEDITED (15-DAY)		OT	CA-ROCHE-2535972		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Pulmonary Mass	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Calcium Carbonate			C				Not Reported
	Cetirizine			C				Not Reported
	Cranberry [Vaccinium Spp.]			C				Not Reported
	Prednisone			C				Not Reported
	Quinapril Hydrochloride			C				Not Reported
	Rabeprazole			C				Not Reported
	Singulair			C				Not Reported
	Olopatadine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393176	EXPEDITED (15-DAY)		HO	CA-ROCHE-2535906		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Ulcer	Rituxan	S	otherwise specified)	
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Ciclosporin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393316	EXPEDITED (15-DAY)		HO	CA-ROCHE-2536017		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Contraindicated Product	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393407	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540921			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393409	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542447		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective;	Actemra			S	Intravenous (not			Not Reported

Treatment Failure			otherwise specified)	
	Apo-Leflunomide	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2020	17393411	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542467		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Feb-2020	17393740	EXPEDITED (15-DAY)		HO	NVSC2020FR028239		73 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatine Phosphokinase Increased; Muscular Weakness; Myalgia; Peripheral Sensorimotor Neuropathy	Doxycycline			S	Oral	200 Mg, Qd		Novartis
	Metronidazole			S	Oral	1500 Mg, Qd		Not Reported
	Atorvastatin			S	Oral	40 Mg, Qd		Not Reported
	Tavanic			S	Oral	1 Df, Qd		Not Reported
	Plaquenil			S	Oral	3 Df, Qd		Not Reported
	Lansoprazole			C	Oral	15 Mg, Qd		Not Reported
	Clopidogrel			C	Oral	75 Mg, Qd		Not Reported
	Fluconazole			C	Oral	200 Mg, Qd		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	11953789	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-069962		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; Condition Aggravated; Cough; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Methotrexate			S	Oral	15 Mg, Qwk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	3.0 Milligram, Qd		Not Reported
	Apo-Prednisone			S	Oral	50.0 Milligram		Not Reported

Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	15 Milligram, Qwk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Gold	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral	15 Mg, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Prednisone	S	Oral	50 Mg, Qd	Not Reported
	Prednisone	S	Oral	3 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	8 Mg/Kg, Qmo	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Losec [Omeprazole]	C	Unknown		Not Reported
	Naprosyn [Naproxen]	C	Unknown		Not Reported
	Celexa [Citalopram Hydrobromide]	C	Unknown		Not Reported
	Crestor	C	Unknown		Not Reported
	Ketoprofen	C	Unknown	100 Mg, Bid	Not Reported
	Citalopram Hydrobromide	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported

	Omeprazole	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	12222790	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-020922		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hepatic Enzyme Increased; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q4wk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Gabapentin			S	Oral	100 Milligram, Bid		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown			Not Reported
	Apo Celecoxib			S	Oral	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Sulfasalazine			S	Oral	2.5 Gram, Qd		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	2.5 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Q3wk		Not Reported
	Apo Gabapentin			S	Oral	100 Milligram, Bid		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Nortriptyline Hydrochloride;Perphenazine			S	Oral	10 Milligram, Qd		Not Reported

Decreased; Treatment Failure	Fentanyl Citrate	S	Epidural		Not Reported
	Fentanyl Matrix	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
	Omega 3 [Fish Oil;Tocopherol]	C	Unknown	1200 Milligram, Bid	Not Reported
	Multivitamin [Ascorbic Acid;Calcium Pantothenate;Ergocalciferol;Nicoti	C	Unknown	Unk	Not Reported
	Tecta	C	Unknown	40 Mg, Qd	Not Reported
	Diphenoxylate	C	Unknown	2.5 Milligram, Qd	Not Reported
	Diphenoxylate	C	Unknown	1 Dosage Form, Qd	Not Reported
	Vitamin D [Ergocalciferol]	C	Unknown	400 Unit, Qd	Not Reported
	Actonel	C	Unknown	36 Milligram, Qwk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	5 Milligram 1 Every 2 Hour	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Q4wk	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Q2wk	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Dosage Form Prn	Not Reported
	Biotin W/Calcium Pantothenate/Colec/06004901/	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	400 International Unit, Qd	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
	Esomeprazole	C	Unknown	400 Milligram, Bid	Not Reported
	Ferrous Gluconate	C	Unknown	300 Milligram, Qd	Not Reported

Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Pyridoxine	C	Unknown	Unk	Not Reported
Nasonex	C	Nasal	2 Dosage Form, Bid	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Milligram, Qd	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Qd	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram 1 Every 1 Hour	Not Reported
Tylenol [Paracetamol]	C	Oral	1000 Milligram, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	1 Dosage Form, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 International Unit, Qd	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid	C	Unknown	Unk Unk, Qd	Not Reported
Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported
Xeljanz	C	Unknown	5 Milligram, Qd	Not Reported
Xeljanz	C	Unknown	5 Milligram	Not Reported
Vitamin B12 Aaa	C	Unknown		Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200 Milligram, Bid	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk Unk, Qd	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported

Trazodone	C	Unknown	Unk	Not Reported
Vitamin A Nos	C	Unknown	Unk	Not Reported
Vitamin B 12	C	Unknown	Unk	Not Reported
Vitamin C Acid	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Milligram 1 Every One Hour	Not Reported
Nexium [Esomeprazole Sodium]	C	Unknown	40 Milligram, Bid	Not Reported
Genteal [Hypromellose]	C	Unknown		Not Reported
Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol	C	Unknown	1 Dosage Form, As Required	Not Reported
Perphenazine	C	Unknown	40 Milligram, Qd	Not Reported
Perphenazine	C	Oral	10 Milligram	Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown	1 Dosage Form, Prn	Not Reported
Vitamin E [Tocopherol]	C	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
Celecoxib	S	Oral	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
Epa Dha 720	C	Unknown	Unk	Not Reported
Fergon	C	Unknown	300 Milligram, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Lomotil [Loperamide Hydrochloride]	C	Unknown	Unk	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown		Not Reported
Omega-3 [Salmo Salar Oil]	C	Unknown	Unk	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Milligram, Bid	Not Reported
Pantoprazole	C	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole	C	Unknown	400 Milligram	Not Reported

	Sodium Ascorbate	C	Unknown	Unk	Not Reported
	Sodium	C	Unknown	Unk	Not Reported
	Cholecalciferol	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	1000 Milligram, Qd	Not Reported
	Risedronate Sodium	C	Unknown	36 Milligram, Qwk	Not Reported
	D-Alpha Tocopheryl Acetate	C	Unknown	1200 Milligram	Not Reported
	Apo-Gabapentin	C	Oral	100 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	12689721	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016400948			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Unknown
	Neoral			S	Oral	20 Mg, Unk		Not Reported
	Plaquenil			S	Oral	20 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	12709758	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0313		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Back Disorder; Blood Albumin Decreased; Condition Aggravated; Contraindicated Product Administered; Diverticulum; Drug Ineffective; Drug Intolerance; Headache; Intestinal Perforation; Loss	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

Of Personal Independence In Daily Activities; Lymphadenopathy; Neck Mass; Off Label Use; Rheumatoid Arthritis; Spinal Operation; Thrombocytosis	Naprosyn	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Abatacept	S	Subcutaneous		Not Reported
	Apo-Methotrexate	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Folic Acid	C	Unknown	4 Days A Week	Not Reported
	Gabapentin	C	Unknown		Not Reported
	Lovastatin	C	Unknown		Not Reported
	Metoprolol	C	Unknown	Strength: 50 Mg	Not Reported
	Vitamin D	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Tramadol Hydrochloride	C	Unknown		Not Reported
	Crestor	C	Unknown		Not Reported
	Naprelan	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Naproxen Sodium	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Rosuvastatin	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	12967538	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anxiety; Arthralgia; Condition Aggravated; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Eye Disorder; Feeling Abnormal; Finger Deformity; Foot Deformity; Gait Disturbance; Gait Inability; Hyperhidrosis; Inflammation; Intervertebral Disc Protrusion; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Off Label Use; Osteoarthritis; Osteoporosis; Peripheral Swelling; Poor Quality Sleep; Rheumatoid Arthritis; Spinal Disorder; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Vomiting; Wrist Deformity	Abatacept			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Winpred			S	Unknown	5 Milligram		Not Reported
	Oxycodone Terephthalate			S	Oral			Not Reported
	Macrogol			S	Unknown			Not Reported
	Apo Prednison			S	Unknown	5 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydromorphone			S	Oral	12 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Percocet [Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol]			C	Unknown			Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Premarin			C	Unknown	Unk		Not Reported
	Lax-A-Day			C	Unknown	Unk		Not Reported
	Monurol			C	Unknown			Not Reported

	Fosfomycin Trometamol	C	Unknown	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	13424028	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017013202		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Cimzia			S	Subcutaneous	Usual Dose For More Than 3 Months		Not Reported
	Enbrel			S		50 Mg, Unk		Not Reported
	Methotrexate			S		Usual Dose For More Than 3 Months		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Tofacitinib Citrate			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported
	Arava			S		Unk		Not Reported
	Leflunomide			S		Usual Dose For More Than 3 Months		Not Reported
	Plaquenil			S		Usual Dose For More Than 3 Months		Not Reported
	Humira			S	Subcutaneous	Usual Dose For More Than 3 Months		Not Reported
	Actemra			S		Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Aspirin			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Cymbalta			C		Unk		Not Reported

	Hydromorphone	C	Unk	Not Reported
	Penicillin	C	Unk	Not Reported
	Acetylsalicylic Acid	C		Not Reported
	Remicade	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	13610813	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1627		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	13840401	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091533			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthropathy;	Orencia			S	Intravenous (not otherwise specified)	1 Dosage Form		Bristol Myers Squibb

Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Prescribed Underdose; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure; Vomiting; X-Ray Abnormal	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Arava	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Prednisone	S	Unknown	10 Milligram	Not Reported
	Prednisone	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Unknown	200 Milligram, Qd	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	14128708	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017042210			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Contraindication To Medical Treatment; Drug Ineffective; Hypersensitivity; Ovarian Disorder; Pulmonary	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported

Toxicity; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine	S	Unk	Not Reported
	Sulfasalazine	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	14308679	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016008213			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol Ra			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol Ra			S		Unk		Not Reported
	Arava			S		20 Mg, Once Daily (Qd)		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S		750 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tylenol			S		Unk		Not Reported
	Enbrel			S		50 Mg, Weekly (Qw)		Not Reported
	Enbrel			S		Unk		Not Reported
	Plaquenil			S		200 Mg, 2x/Day (Bid)		Not Reported
	Sulfasalazine			S	Oral	2000 Mg, Unk For 6 Months		Not Reported
	Acetaminophen			S		325 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 2x/Day (Bid)		Not Reported
	Methotrexate			S		25 Mg/ Ml, Weekly (Qw)		Not Reported
	Methotrexate			S		20 Milligram, Weekly (Qw)		Not Reported

Xeljanz	C	Oral	5 Mg, 2x/Day (Bid)		Not Reported
Synthroid	C		Unk		Not Reported
Leflunomide	C		Unk		Not Reported
Meloxicam	C		Unk, Weekly (Qw)		Not Reported
Tylenol With Codein #3	C				Not Reported
Acetaminophen W/Codeine	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	14704614	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018012672		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Drug Intolerance; Finger Deformity; Headache; Hyperhidrosis; Joint Swelling; Limb Discomfort; Nausea; Night Sweats; Off Label Use; Osteoarthritis; Palpitations; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Arava			S	Oral	20 Mg, Once Daily (Qd)		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Ev 4 Weeks		Not Reported
	Plaquenil			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium			S	Oral	17.5 Mg, Weekly (Qw)		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg, Weekly (Qw)		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Ev 2 Weeks(Qow)		Not Reported
	Coversyl			C				Not Reported
	Ergocalciferol			C		2000 International Unit		Not Reported
	Leucovorin			C				Not Reported
	Folinic Acid			C				Not Reported
	Perindopril Erbumine			C	Oral	4 Milligram, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	14909752	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018020609			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S		Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Codeine			S		Unknown		Not Reported
	Plaquenil			S	Oral	400 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw) For 5 Years		Not Reported
	Humira			S	Subcutaneous	40 Mg, For 9 Years		Not Reported
	Methotrexate			S		25 Mg, Weekly (Qw) For 15 Years		Not Reported
	Orencia			S		Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Monthly (Qm) For 127 Days		Not Reported
	Sulfasalazine			S		Unknown Dose		Not Reported
	Hydroxychloroquine			S		400 Mg, Unk		Not Reported
	Xeljanz			C		Unknown		Not Reported
	Prednisone			C		Unknown		Not Reported
	Adalimumab			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	15285301	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2018CA021912			Unknown	CAN

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

Abdominal Pain; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Off Label Use; Treatment Failure; Vomiting	Infliximab Pfizer (Unknown)	S	Unknown	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Qd		Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd		Not Reported
	Morphine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	15922651	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653466-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Gabapentin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	15935383	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656801-00		36 YR	Female	CAN

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

Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Humira	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Therapy Duration-5 Month	Not Reported
	Enbrel	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	Therapy Duration-6 Month	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Rabeprazole Sodium	C	Oral		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	15975815	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013003		66 YR	Male	CAN

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

C-Reactive Protein Increased; Joint Swelling; Off Label Use; Pneumonia; Treatment Failure	Orencia	S	Unknown	Unk	Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Lidocaine Hydrochloride	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5.0 Milligram, Bid	Not Reported
	Cephalexin [Cefalexin]	C	Unknown	500 Milligram, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16100906	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1025445		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram		Mylan
	Methotrexate			S	Oral	20 Milligram		Mylan
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Mylan
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Mylan
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Mylan
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Mylan

Apo-Hydroxyquine	S	Oral	Unk	Mylan
Apo-Hydroxyquine	S	Unknown	Unk	Mylan
Apo-Hydroxyquine	S	Unknown	Unk	Mylan
Hydroxychloroquine	S	Oral	20 Milligram	Mylan
Hydroxychloroquine	S	Oral	Unk	Mylan
Hydroxychloroquine	S	Oral	Unk	Mylan
Hydroxychloroquine	S	Subcutaneous	Unk	Mylan
Hydroxychloroquine	S	Unknown	Unk	Mylan
Methotrexate Sodium	S	Subcutaneous	20 Milligram	Mylan
Methotrexate Sodium	S	Subcutaneous	20 Milligram	Mylan
Methotrexate Sodium	S	Subcutaneous	20 Milligram	Mylan
Methotrexate Sodium	S	Subcutaneous	Unk	Mylan
Methotrexate Sodium	S	Oral	20 Milligram	Mylan
Methotrexate Sodium	S	Oral	20 Milligram	Mylan
Methotrexate Sodium	S	Oral	20 Milligram	Mylan
Methotrexate Sodium	S	Oral	20 Milligram	Mylan
Methotrexate Sodium	S	Oral	20 Milligram	Mylan
Neoral	S	Subcutaneous	Unk	Mylan
Neoral	S	Subcutaneous	Unk	Mylan
Neoral	S	Subcutaneous	Unk	Mylan
Neoral	S	Oral	Unk	Mylan
Neoral	S	Oral	Unk	Mylan
Humira	S	Intravenous (not otherwise specified)	Solution Subcutaneous	Mylan
Humira	S	Unknown	Solution Subcutaneous	Mylan
Humira	S	Subcutaneous	Unk	Mylan
Humira	S	Subcutaneous	Unk	Mylan
Humira	S	Subcutaneous	Solution Subcutaneous	Mylan
Ciclosporin	S	Unknown	Unk	Mylan

Ciclosporin	S	Subcutaneous	Unk	Mylan
Enbrel	S	Subcutaneous	50 Milligram, Qw	Mylan
Enbrel	S	Subcutaneous	50 Milligram, Qw	Mylan
Enbrel	S	Subcutaneous	50 Milligram, Qw	Mylan
Rituxan	S	Intravenous (not otherwise specified)	Unk	Mylan
Rituxan	S	Intravenous (not otherwise specified)	Unk	Mylan
Remicade	S	Intravenous (not otherwise specified)	3 Milligram	Mylan
Remicade	S	Intravenous (not otherwise specified)	3 Milligram	Mylan
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Mylan
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Mylan
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Mylan
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Mylan
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Mylan
Apo-Leflunomide	S	Oral	Unk	Mylan
Apo-Leflunomide	S	Unknown	Unk	Mylan
Orencia	S	Subcutaneous	125 Milligram	Mylan
Orencia	S	Subcutaneous	125 Milligram	Mylan
Orencia	S	Subcutaneous	125 Milligram	Mylan
Leflunomide	S	Unknown	Unk	Mylan
Leflunomide	S	Unknown	Unk	Mylan
Sulfasalazine	S	Oral	Unk	Mylan
Plaquenil /00072603/	S	Oral	Unk	Mylan
Plaquenil /00072603/	S	Unknown	Unk	Mylan

Rituximab	S	Intravenous (not otherwise specified)	Unk		Mylan
Rituximab	S	Oral	Unk		Mylan
Simponi	S	Subcutaneous	Unk		Mylan
Xeljanz	C	Unknown	2 Every 1 Day		Mylan
Xeljanz	C	Oral	10 Milligram, Qd (5 Mg, Bid)		Mylan
Xeljanz	C	Unknown	2 Ot, Qd		Mylan
Xeljanz	C	Oral	10 Milligram, Qd		Mylan
Xeljanz	C	Oral	10 Milligram, Qd (5 Mg, Bid)		Mylan
Xeljanz	C	Unknown	Unk		Mylan
Xeljanz	C	Oral	10 Milligram, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16252372	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-039070		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Neutropenia; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Urinary Tract Infection	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Unknown	776 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qwk		Not Reported
	Methotrexate			C	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown	400 Milligram, Qwk		Not Reported

	Xeljanz		C	Unknown	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate		C	Unknown	400 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16269769	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20190409745			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Otezla			S	Oral			Celgene
	Otezla			S				Celgene
	Cosentyx			S	Unknown			Not Reported
	Cosentyx			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Stelara			S				Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16438452	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15073			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus;	Etanercept			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported

Systemic Lupus Erythematosus	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Arava	S	Oral	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Unknown	Not Reported
	Desoximetasone	S	Oral	Unknown	Not Reported
	Folic Acid	S	Unknown	Unknown	Not Reported
	Fosamax	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Orencia	S	Subcutaneous	Unknown	Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16489780	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2059		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Blood Creatinine Decreased; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported

Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Photophobia; Rheumatoid Arthritis; Synovitis; Tinnitus; Vision Blurred; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Cyclic: 4 Times/Week	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydromorphone Hydrochloride	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown	Dose: 15.5 (Units Unknown)	Not Reported
	Plaquenil Sulfate	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen	S	Oral		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Dilaudid	S	Unknown		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Diphenhydramine Hydrochloride	C	Unknown		Not Reported
	Fosavance	C	Unknown		Not Reported
	Hydrocortisone	C	Unknown		Not Reported
	Hyzaar	C	Unknown		Not Reported

	Methylprednisolone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16839343	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-088706		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder; Lung Disorder; Product Dispensing Error; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qcycle		Not Reported
	Arava			S	Unknown	10 Milligram, Qcycle		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, 1 Every 1 Week		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	1000 Milligram, 2 Every 1 Day		Not Reported
	Prednisone			S	Unknown	1 Milligram, Every 1 Day		Not Reported
	Prednisone			S	Unknown	5 Milligram		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Q12h		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, 2 Every 1 Day		Not Reported
	Xeljanz			S	Oral	5 Milligram, 2 Every 1 Day		Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C	Unknown	2 Dosage Form, Qcycle		Not Reported

	Asa	C	Unknown	325 Milligram	Not Reported
	Bisoprolol	C	Unknown	5 Milligram, Every 1 Day	Not Reported
	Endocet	C	Unknown	Unk	Not Reported
	Endocet	C	Unknown	1 Dosage Form , 2 Every 1 Days	Not Reported
	Folic Acid	C	Unknown	5 Milligram, Qcycle	Not Reported
	Indomethacin [Indometacin]	C	Unknown	Unk	Not Reported
	Macrogol	C	Unknown	Unk	Not Reported
	Metoprolol	C	Unknown	75 Milligram, 2 Every 1 Day	Not Reported
	Naproxen Sodium	C	Unknown	1000 Milligram, Qcycle	Not Reported
	Pennsaid	C	Topical	Unk	Not Reported
	Vitamin B 12	C	Unknown	Unk	Not Reported
	D-Alpha Tocopherol	C	Unknown	12000 Milligram, Qd	Not Reported
	Fish Oil	C	Unknown	12000 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	16933922	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2796105-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; Unevaluable Event; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17225723	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2019M1131678		63 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Disease Progression; Dyspnoea; Fatigue; Gastrointestinal Disorder; Interstitial Lung Disease; Product Use In Unapproved Indication; Pulmonary Embolism	Methotrexate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S		Unk		Mylan
	Rituximab			S	Unknown	1 G (Twice, 2 Week Apart), Cyclic(9 Cycles)		Mylan
	Rituximab			S	Unknown	Unk		Mylan
	Rituximab			S	Unknown	1 G, Bid		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17297595	EXPEDITED (15-DAY)		OT	CA-LUPIN HEALTHCARE (UK) LIMITED-2020-00254		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Losartan Potassium			S	Unknown	Unk		Lupin
	Moxifloxacin Hydrochloride			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Cephalexin			S	Unknown	Unk (Tablet)		Lupin
	Cephalexin			S	Unknown	Unk		Lupin
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Clindamycin Hydrochloride			S	Unknown	Unk		Not Reported

	Codeine	S	Unknown	Unk	Not Reported
	Enalapril Maleate	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram Every 1 Week	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Penicillin G [Benzylpenicillin]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Avelox	S	Unknown	Unk	Not Reported
	Penicillin Nos	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Cipro [Ciprofloxacin]	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Saccharated Iron Oxide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17356419	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1010578		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Bicytopenia;	Omeprazole			S	Unknown	Unk		Not Reported

Dermatitis Psoriasiform; Dna Antibody; Drug Ineffective; Evans Syndrome; General Physical Health Deterioration; Hypergammaglobulinaemia; Lymphadenopathy; Pericarditis; Pyrexia; Scar; Skin Lesion; Subacute Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus	Methotrexate	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Mylan
	Azathioprine	C		Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17393907	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543740			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen;Codeine Phosphate			C				Not Reported

	Meloxicam	C			Not Reported
	Methotrexate	C	Unknown		Not Reported
	Synthroid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17393996	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2537096			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394059	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3265441-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Rituximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394178	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538089			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Not Reported
	Methotrexate			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394264	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537887		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394399	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536713		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Hypersensitivity; Drug	Actemra			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Rheumatoid Arthritis; Spleen Disorder; Urticaria	Enbrel		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Cimzia		C	Unknown	Not Reported
	Sulfasalazine		C	Unknown	Not Reported
	Methotrexate		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394502	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Spiriva			S	Unknown			Boehringer Ingelheim
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lipitor			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral			Not Reported
	Zenhale			S	Unknown			Not Reported
	Zenhale			S	Unknown	Aerosol, Metered Dose		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394504	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1181893		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Ciclosporin			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous	20 Mg		Barr
	Methotrexate			S				Barr

	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Neoral	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Endocervical		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394588	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537191			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394661	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1179329			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Urine Present; Drug Tolerance; Intentional Product Use Issue	Ciclosporin			S	Unknown			Ivax
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394663	EXPEDITED (15-DAY)		DS, HO, OT	CA-TEVA-2020-CA-1179313		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Alendronate Sodium			S	Unknown			Actavis
	Ciclosporin			S	Unknown			Ivax
	Codeine			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Actavis
	Ibuprofen			S	Oral	600 Milligram Daily;		Actavis
	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Ibuprofen			S	Oral			Not Reported
	Apremilast			S	Unknown	120 Milligram Daily;		Not Reported
	Apremilast			S				Not Reported
	Apremilast			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
Sulfasalazine	S	Endocervical		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Subcutaneous		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Oxycodone	C	Unknown		Not Reported
Benadryl	C	Unknown		Not Reported
Colchicine	C	Unknown		Not Reported
Dexilant	C	Oral		Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Gravol	C	Unknown		Not Reported
Mogadon	C	Oral		Not Reported
Nitrazepam	C	Oral		Not Reported
Prednisone	C	Unknown		Not Reported
Uloric	C	Oral		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537374		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain;	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported

Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394679	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540899			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394727	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-007436		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394921	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537338			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Cough; Drug Ineffective; Influenza; Nasopharyngitis; Nausea; Psoriasis; Rash	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394929	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0727			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Pain; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394930	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Esomeprazole Magnesium-Naproxen Sodium			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17394934	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3265597-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Gastric Disorder; Therapeutic Product Effect Decreased; Visual Field Defect	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395045	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538042			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395100	EXPEDITED (15-DAY)		OT	CA-ROCHE-2537878			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Blood Cholesterol Increased; Bronchitis; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Hypertension; Joint Swelling; Laboratory Test Abnormal; Mucosal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

Inflammation; Pneumonia; Sleep Disorder; Treatment Failure	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Calcium Carbonate	C	Oral	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Hydromorphone	C	Oral	Not Reported
	Methotrexate	C	Oral	Not Reported
	Naproxen	C	Unknown	Not Reported
	Tylenol Arthritis Pain	C	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Prednisolone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395178	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540895			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395295	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542486		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395317	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542479		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395319	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542481		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Failure	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Neoral	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395387	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539792			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17395477	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542443		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Contraindicated Product Administered; Rash; Treatment Failure; Urticaria	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17396501	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-007467			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased;	Orencia			S	Unknown			Bristol Myers Squibb

Pneumonia; Rheumatoid Arthritis	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17396502	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-007504			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituximab	S	Intravenous drip	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17396506	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-007561			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Limb Discomfort; Loss Of Consciousness; Mobility Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17396588	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020052301			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Pancytopenia; Weight	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer

Decreased	Sulfasalazine		S	Unknown	1 G, 1 Every 12 Hours	Pfizer
	Leflunomide		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		S	Unknown		Not Reported
	Hydroxychloroquine		C	Unknown	400 Mg, Unk	Not Reported
	Infliximab		C	Intravenous (not otherwise specified)	300 Mg, 1 Every 6 Weeks	Not Reported
	Infliximab		C	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
	Infliximab		C	Intravenous (not otherwise specified)	300 Mg, 1 Every 8 Weeks	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	Unk Unk, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17396931	EXPEDITED (15-DAY)		DE	US-ENDO PHARMACEUTICALS INC-2020-001252		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Toxicity To Various Agents	Ibuprofen			S	Oral	Unk Unknown, Unknown		Par
	Hydroxychloroquine			S	Oral	6 G, Unknown		Not Reported
	Naproxen			S	Oral	Unk Unknown, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17397440	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050946		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S		100 Mg, Unk		Not Reported
	Celebrex			S				Not Reported
	Celebrex			S				Not Reported
	Enbrel			S				Not Reported

	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S		1 Ml, Weekly (Qw)	Not Reported
	Plaquenil	S			Not Reported
	Apo-Prednisone	S		7 Mg, Once Daily (Qd)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	7 Milligram, Once Daily (Qd); Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17398197	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2020054650			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Asthma; Blister; Dyspepsia; Gastric Disorder; Oral Herpes; Oropharyngeal Pain; Pain In Extremity; Peripheral Swelling	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Prednisone			C		25 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17398288	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200200441			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported

Remicade	S	Intravenous drip		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Arava	C	Oral		Not Reported
Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Feb-2020	17399182	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540688			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rash; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	12811220	EXPEDITED (15-DAY)		OT	CA-UCBSA-2015025966		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Off Label Use; Viral Upper	Cimzia			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	1 Df, Weekly (Qw)		Not Reported
	Tofacitinib			S	Oral	5 Mg, 2x/Day (Bid)		Not Reported

Respiratory Tract Infection	Tofacitinib	S		Unk	Not Reported
	Tofacitinib	S	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Tofacitinib	S	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Tofacitinib	S	Oral	5 Mg, 2x/Day (Bid)	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk, Powder For Solution	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Arava	C		Unk	Not Reported
	Prednisone	C	Oral		Not Reported
	Xeljanz	C	Oral	5 Milligram, 2x/Day (Bid)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	14299205	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050904		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Ear Infection; Fatigue; Fine Motor Skill Dysfunction; Malaise; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	400 Mg, Weekly (Qw)		Not Reported
	Arava			S		20 Mg, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw)		Not Reported
	Methotrexate			S		15 Mg, Weekly (Qw)		Not Reported
	Orencia			S		125 Mg, Unk		Not Reported
	Plaquenil			S		200 Mg, 2x/Day (Bid)		Not Reported
	Apo-Prednisone			S		5 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Prednisone			S		Unk		Not Reported
	Prevacid			C		30 Mg, Once Daily (Qd)		Not Reported

	Folate	C	1 Milligram, Once Daily (Qd)	Not Reported
	Actonel	C	35 Mg, Weekly (Qw)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	14311631	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050957		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; C-Reactive Protein Increased; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Spinal Operation; Surgery; Thrombocytosis	Cimzia			S	Subcutaneous	Unk		Not Reported
	Abatacept			S	Subcutaneous	125 Mg, Unk		Not Reported
	Apo-Methotrexate			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw)		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly (Qw)		Not Reported
	Naprosyn			S		500 Mg, 2x/Day (Bid)		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Weekly (Qw)		Not Reported
	Plaquenil			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Ergocalciferol			C				Not Reported
	Folic Acid			C				Not Reported
	Gabapentin			C				Not Reported
	Lovastatin			C				Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
	Prednisone			S		20 Milligram		Not Reported
	Prednisone			S		2.5 Milligram, Weekly (Qw)		Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Tramadol Hydrochloride			C				Not Reported
	Tofacitinib			C				Not Reported
	Naproxen			C				Not Reported
	Naproxen Sodium			C				Not Reported
	Vitamin D3			C		Unk		Not Reported
	Apo-Prednisone			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	125 Milligram, Weekly (Qw)		Not Reported

Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	14496258	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007159		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Influenza; Injection Site Pain; Off Label Use; Pain; Pain In Extremity; Rheumatoid Arthritis; Skin Burning Sensation; Skin Exfoliation	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Allopurinol			C	Unknown			Not Reported
	Hydromorph Contin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	14921585	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044684			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Gait Inability; Joint Swelling; Mobility Decreased; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Tramadol Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Tramadol Hydrochloride			S	Unknown	Unk		Not Reported
	Arava			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Qwk		Not Reported

Methotrexate	C	Oral	15 Unk, Unk		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Simponi	C	Subcutaneous			Not Reported
Xeljanz	C	Oral	5.0 Milligram, Bid		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15112426	EXPEDITED (15-DAY)		OT	CA-UCBSA-2018028967			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S		25 Mg, Weekly (Qw); Solution		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Tofacitinib Citrate			S		Unk		Not Reported
	Tofacitinib			S				Not Reported
	Leflunomide			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15365414	NON-EXPEDITED			US-PFIZER INC-2018362153		76 YR	Female	USA

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

Drug Hypersensitivity	Enbrel	S	Unk	Pfizer
	Methotrexate Sodium	S	Unk	Pfizer
	Arava	S	Unk	Not Reported
	Plaquenil	S	Unk	Not Reported
	Rituximab	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15394855	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016039015		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Df, Weekly (Qw)		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate Sodium			S				Not Reported
	Methotrexate Sodium			S	Oral	Solution		Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Sulfasalazine			S				Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	1 Dosgae Form, Ev 2 Weeks(Qow)		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported

Prednisone	C	Oral	6 Mg, Once Daily (Qd)		Not Reported
Prednisone	C	Oral	10 Mg, Once Daily (Qd)		Not Reported
Tylenol	C		Unk		Not Reported
Advil	C		Unk		Not Reported
Mefenamic Acid	C		Unk		Not Reported
Dequalinium Chloride	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15411214	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186666		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral	1.0 Dosage Forms		Not Reported
	Varenicline Tartrate			S	Oral	1 Doses Form		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Oxycodone Hydrochloride			C	Unknown			Not Reported

	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	Not Reported
	Rosuvastatin Calcium	C	Oral	Not Reported
	Valtrex	C	Oral	Not Reported
	Valtrex	C	Unknown	Not Reported
	Naproxen	C	Oral	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15608532	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA201843216			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication;	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 G, Unk		Shire
	Infliximab			S	Unknown	5 Mg, Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg/Kg, 1x/Week		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, 1x/Day:Qd		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, 4x A Week		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Mg/Kg, 1x/Day:Qd		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, 1x/Week		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, 1x A Month		Not Reported
	Prednisone			S	Oral	5 Mg, 2x/Day:Bid		Not Reported
	Prednisone			S	Oral	3 Mg, Unk		Not Reported

Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Tocilizumab		S	Intravenous (not otherwise specified)	280 Mg, Unk	Not Reported
	Sulfasalazine		S	Oral	250 Mg, 1x/Day:Qd	Not Reported
	Actemra		S	Intravenous (not otherwise specified)	280 Mg, 1x/Week	Not Reported
	Actemra		S	Intravenous (not otherwise specified)	280 Mg, 1x/2wks	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Kineret		S	Subcutaneous	50 Milligram, 1x/Day:Qd	Not Reported
	Apo-Naproxen		S	Unknown	Unk	Not Reported
	Apo-Naproxen		S	Unknown	Unk	Not Reported
	Apo-Prednisone		S	Oral	3.0 Milligram, 2x/Day:Bid	Not Reported
	Apo-Prednisone		S	Oral	5.0 Milligram	Not Reported
	Triamcinolone Acetonide		S	Intra-articular	Unk	Not Reported
	Triamcinolone		C	Other	Unk	Not Reported
	Triamcinolone Hexacetonide		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15775641	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0586		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Carpal Tunnel Syndrome; Drug Ineffective; Fibromyalgia; General Physical Health Deterioration; Joint Swelling; Liver Function Test Increased; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Radicular Pain; Rheumatoid Arthritis;	Methotrexate (Trade Name Unknown)			S	Unknown	17.5 To 25 Mg		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Spinal Stenosis	Enbrel	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S			Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Tramacet	S	Unknown		Not Reported
	Aclasta	S	Intravenous (not otherwise specified)	Single	Not Reported
	Tramadol/Acetaminophen	S	Oral		Not Reported
	Nortriptylin	C	Unknown	Once At Bedtime	Not Reported
	Nortriptylin	C	Unknown	Bedtime	Not Reported
	Metformin	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Lorazepam	C	Unknown	Once Nightly	Not Reported
	Vagifem	C	Unknown		Not Reported
	Lyrica	C	Oral		Not Reported
	Premarin	C	Unknown	Strength: 0.625mg	Not Reported
	Vitamin D	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Depomedrol	C	Intramuscular		Not Reported
	Depomedrol	C	Subcutaneous		Not Reported
	Depomedrol	C	Subcutaneous		Not Reported
	Tylenol Arthritis	C	Unknown		Not Reported
	Actonel Dr	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Methylprednisolone Acetate	C	Unknown		Not Reported
	Nortriptyline Hydrochloride	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported

	Risedronate Sodium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15809559	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2616794-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Victim Of Crime	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C				Not Reported
	Sulfasalazine			C	Oral			Not Reported
	Synthroid			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	15975888	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-016370			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Iron Abnormal; Condition Aggravated; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	125 Milligram, Qd		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qwk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported

Pain; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Gold	S	Unknown		Not Reported
	Imuran [Azathioprine]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Certolizumab	S	Unknown	200 Mg, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qwk	Not Reported
	Humira	S	Unknown	400 Mg, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	640 Mg, Q4wk	Not Reported
	Actemra	S	Unknown	640 Mg, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	640 Milligram, Qmo	Not Reported
	Actemra	S	Unknown	64 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Oral	Unk, Qcycle	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	300 Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	200 Milligram, Qwk	Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qwk	Not Reported
	Apo-Cyclosporine	S	Oral		Not Reported
	Lyrica	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Ciclosporin	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qwk	Not Reported

Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Milligram, Qwk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulphate	S	Oral	400 Milligram, Qd	Not Reported
Certolizumab Pegol	S	Unknown	200 Milligram, Q2wk, Cyclical	Not Reported
Certolizumab Pegol	S	Subcutaneous	200 Milligram, Qwk, Cyclical	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous		Not Reported
Tocilizumab	S	Unknown	640 Milligram, Qwk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
Leflunomide	S	Unknown	Unk Unk, Qd	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Piroxicam	C	Unknown		Not Reported
Prednisone	C	Oral		Not Reported
Folic Acid	C	Unknown	5 Milligram	Not Reported
Methotrexate	C	Oral	25 Milligram, Qwk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16447545	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15412			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Etanercept			S	Unknown	Unknown		Not Reported

C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Actemra	S	Unknown	Unknown	Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16631284	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA201923301			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram		Shire
	Human Normal Immunoglobulin			S	Unknown	Unk		Shire
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, 1x/2wks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, 1x/Week		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, 4x A Week		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Milligram/Kilogram, 1x/Day:Qd		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, 1x/Week		Not Reported
	Infliximab			S	Unknown	5 Milligram		Not Reported
	Kineret			S	Subcutaneous	50 Milligram, 1x/Day:Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram/Sq. Meter,		Not Reported

				1x/Week	
	Naproxen	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
	Prednisone	S	Oral	5 Milligram, 2x/Day:Bid	Not Reported
	Prednisone	S	Oral	3 Milligram	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, 1x/Day:Qd	Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous	150 Milligram, 1x/Day:Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16631288	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA201923310			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis;	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram		Shire
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, 4x A Week		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Milligram/Kilogram, 1x/Day:Qd		Not Reported
	Infliximab			S	Unknown	5 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram, 1x/Week		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram/Sq. Meter,		Not Reported

Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting				1x/Week	
	Naproxen	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
	Prednisone	S	Oral	3 Milligram, 2x/Day:Bid	Not Reported
	Prednisone	S	Oral	5 Milligram, 2x/Day:Bid	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, 1x/Day:Qd	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unk	Not Reported
	Kineret	S	Subcutaneous	50 Milligram, 1x/Day:Qd	Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, 1x/Day:Qd	Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16689275	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-21899			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Treatment Failure; Vomiting	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Morphine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16842040	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27131		64 YR	Female	CAN

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

Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Infliximab	S	Unknown	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Acetaminophen	C	Unknown	Unknown	Not Reported
	Cortisone Infiltration	C	Unknown	Unknown	Not Reported
	Dexamethasone	C	Unknown	Unknown	Not Reported
	Gabapentin	C	Unknown	Unknown	Not Reported

Reactine	C	Unknown	Unknown		Not Reported
Cetirizine Hydrochloride	C	Unknown	Unknown		Not Reported
Desoximetasone	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16865618	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083770		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Orencia			S	Unknown			Bristol Myers Squibb
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Unknown	10 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Sarilumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

Tofacitinib	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Rabeprazole Sodium	C	Oral	20 Mg, Unk		Not Reported
Methotrexate	C	Oral			Not Reported
Prednisone	C	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16946347	EXPEDITED (15-DAY)		OT	NVSC2019FR010234		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Use In Unapproved Indication; Urticarial Vasculitis	Omalizumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Anakinra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	16971655	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20191006447			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nausea; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; White Blood Cell	Otezla			S	Oral	60 Milligram		Celgene
	Actemra			S	Unknown			Not Reported
	Cosentyx			S	Unknown	150 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Orencia			S	Subcutaneous	125 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Sulfasalazine			C	Unknown	2 Gram		Not Reported

Count Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17146210	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2016038606		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Off Label Use; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Celebrex			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Dilaudid			S		Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S		Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Voltaren			S		Unk		Not Reported
	Diclofenac			S		Unk		Not Reported
	Diclofenac			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Diclofenac Potassium			S		Unk		Not Reported
	Rituximab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17181501	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6011		61 YR	Female	CAN

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

Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)		S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Orencia		S	Unknown	Not Reported
	Xeljanz		S	Unknown	Not Reported
	Xeljanz		S	Oral	Not Reported
	Actemra		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Arava		S	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17284429	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000044			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Demerol			S	Unknown	Unk		Validus
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported

Levofloxacin	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Azithromycin	S	Unknown	250 Mg, Qd	Not Reported
Cyclophosphamide	S	Unknown	2000, Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Imuran /00001501/	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
Ezetrol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399264	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017051199		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Astigmatism; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective For Unapproved Indication; Dyspnoea; Hypersensitivity; Impaired Work Ability; Pain; Paraesthesia; Swelling; Therapeutic Product Effect Decreased; Vomiting	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Prednisone	C		10 Milligram, Once Daily (Qd)	Not Reported
Sulfadiazine	S		Unk	Not Reported
Baclofen	S		10 Milligram	Not Reported
Baclofen	S		Unk	Not Reported
Calcium Carbonate	C			Not Reported
Folic Acid	C			Not Reported
Hydromorphone	C			Not Reported
Methotrexate Sodium	S	Subcutaneous	Unk, Weekly (Qw)	Not Reported
Naproxen	S	Oral	500 Milligram, 2x/Day (Bid)	Not Reported
Tylenol [Paracetamol]	C			Not Reported
Vitamin D [Ergocalciferol]	C			Not Reported
Xeljanz	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399302	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000609			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Therapy Non-Responder	Hydroxychloroquine			S		Unk		Concordia
	Doxycycline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399305	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000607			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Therapy Non-Responder	Hydroxychloroquine			S		Unk		Concordia
	Doxycycline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399341	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000608			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Therapy Non-Responder	Hydroxychloroquine			S		Unk		Concordia
	Doxycycline			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399434	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539634		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Flushing; Heart Rate Decreased; Herpes Zoster; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Discolouration; Skin Disorder; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	8.0 Years		Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lasix [Furosemide]			C	Unknown			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Naprosyn [Naproxen]			C				Not Reported
	Oxycontin			C				Not Reported
	Oxyneo			C				Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399535	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538479		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration;L- 6.0 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration;- 4.0 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Therapy Duration:- 730.0		Not Reported
	Cephalexin [Cefalexin]			C	Unknown			Not Reported
	Perindopril			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399635	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538069			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Hepatic	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Cirrhosis; Synovitis; Treatment Failure; X-Ray Abnormal	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399645	EXPEDITED (15-DAY)		DS, HO, LT	CA-ROCHE-2538087		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Intravenous drip			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User			otherwise specified)		
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5.0 Months	Not Reported
	Infliximab	S	Unknown	9.0 Months	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Kineret	S	Subcutaneous	3.0 Years, Kineret 100 Mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Kineret	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	10.0 Years	Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	3.0 Months	Not Reported
	Orencia	S	Respiratory (inhalation)		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S			Not Reported
	Triamcinolone Acetonide	S	Intra-articular		Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399649	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543681			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399692	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-008175			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb

Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram (One Every Two Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399767	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported

Cimzia	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Imuran [Azathioprine]	S	Unknown	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Lyrica	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Piroxicam	C		Not Reported
Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399847	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543705		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported

Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Imuran [Azathioprine]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399861	EXPEDITED (15-DAY)		DE, OT	US-CIPLA LTD.-2020US00998			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suspected Suicide; Toxicity To Various Agents	Cyclobenzaprine			S	Oral	Unk		Invagen
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Amitriptyline			S	Oral	Unk		Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride			S	Oral	Unk		Not Reported
	Tramadol			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17399923	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-006227		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Interaction; Dyspnoea; Feeling Abnormal; Head	Fluoxetine Dispersible Tablet			S	Unknown	1 Dosage Form, Once A Day		Aurobindo
	Plaquenil			S	Unknown	200 Milligram, Once A Day		Not Reported

Discomfort; Near Death Experience; Palpitations; Reading Disorder

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400029	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0757			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400030	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0734			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Interstitial Lung Disease; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400078	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540883		34 YR	Female	CAN

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

Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Actemra		S	Unknown		Not Reported
	Bactrim		S	Unknown		Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown	730.0	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400088	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0744			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Nausea; Neuropathy Peripheral	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400143	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540891			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400178	EXPEDITED (15-DAY)		OT	SE-ORION CORPORATION ORION PHARMA-20_00008421		59 YR	Female	SWE

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

Deafness Neurosensory; Dizziness; Ear Discomfort; Nausea; Product Use In Unapproved Indication; Tinnitus	Methotrexate (Trade Name Unknown)	S	Unknown	"Nov 2016 Mtx Was Raised To 8 Tab / Week"	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	7 Tablet	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	6 Tablet	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	6 Tabs. Methotrexate / Week +5 Mg Prednisolone For Many Years	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisolone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400296	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542446		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Endocervical			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported

Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400415	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540935		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400475	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1182316			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Gabapentin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17400913	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546059		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	730.0 Days		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C			Not Reported
	Actemra	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401102	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543630		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Neck Pain	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401148	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020004631		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal	Cimzia			S	Subcutaneous			Not Reported
	Arava			S		20 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported

Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Hydroxyquinoline Sulfate	S			Not Reported
	Leflunomide	S		20 Milligram	Not Reported
	Methotrexate	S		25 Milligram	Not Reported
	Neoral	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S			Not Reported
	Rapamune	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine	S		1 Gram	Not Reported
	Tacrolimus	S	Oral	2 Milligram, 2x/Day (Bid)	Not Reported
	Tacrolimus	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported
	Imuran [Azathioprine Sodium]	C		25 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401431	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543719			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Gabapentin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401480	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543689			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401574	EXPEDITED (15-DAY)		DE, OT	US-CIPLA LTD.-2020US00792			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Suspected Suicide; Toxicity To Various Agents	Meloxicam			S	Oral	Unk		Cipla
	Cetirizine			S	Oral	Unk		Cipla
	Hydroxyzine			S	Oral	Unk		Invagen
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Butalbital, Acetaminophen & Caffeine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401828	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016038081		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Ear Infection; Fatigue; Fine Motor Skill Dysfunction; Malaise; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Swelling	Cimzia			S	Subcutaneous	400 Mg, Weekly (Qw)		Not Reported
	Arava			S		20 Mg, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly (Qw) 3.0 Month(S)		Not Reported
	Methotrexate Sodium			S		15 Mg, Weekly (Qw) 3.0 Month(S)		Not Reported
	Orencia			S		125 Mg, Unk		Not Reported
	Plaquenil			S		200 Mg, 2x/Day (Bid)		Not Reported
	Apo-Prednisone			S		5 Milligram		Not Reported
	Prednisone			S		Unk		Not Reported
	Prevacid			C		30 Mg, Once Daily (Qd)		Not Reported
	Actonel			C		35 Mg, Weekly (Qw)		Not Reported
	Folate			C		1 Mg, Once Daily (Qd)		Not Reported
	Folate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542463		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Humira	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Neoral	S	Unknown	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401907	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541324		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Intolerance; Fatigue; Hand Deformity; Headache; Joint Swelling; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17401991	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541350		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	Therapy Durationl- 6.0 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Durationl- 4.0 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Therapy Durationl-730.0		Not Reported
	Cephalexin [Cefalexin]			C	Unknown			Not Reported
	Perindopril			C	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17402084	EXPEDITED (15-DAY)		OT	NVSC2020CA033448		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Liver Function Test Increased; Palpitations; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	1 Df (10 Mg), Qw		Not Reported
	Methotrexate			S	Oral	1 Df (15 Mg), Qw		Not Reported
	Methotrexate			S	Oral	1 Df (20 Mg), Qw		Not Reported
	Methotrexate			S	Oral	1 Df (25 Mg), Q3w		Not Reported

Adalimumab	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Infliximab	S	Unknown	600 Mg, Unknown (1 Every Six Weeks)	Not Reported
Sulfasalazine	S	Unknown	2 Df (1 G), Qd	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qmo	Not Reported
Humira	S	Subcutaneous	40 Mg, Unknown	Not Reported
Acetaminophen And Codeine	C	Unknown	325 Mg, Unknown	Not Reported
Amitriptyline Hydrochloride	C	Unknown	Unk	Not Reported
Baclofen	C	Unknown	Unk	Not Reported
Betahistine Hydrochloride	C	Unknown	Unk	Not Reported
Caffeine	C	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Clonidine Hydrochloride	C	Unknown	Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Unk	Not Reported
Fluticasone Propionate	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	1 Df (5 Mg), Qd	Not Reported
Folinic Acid	C	Unknown	Unk	Not Reported
Gabapentin	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Losartan	C	Unknown	Unk	Not Reported
Metoprolol Tartrate	C	Unknown	Unk	Not Reported
Mometasone Furoate	C	Unknown	Unk	Not Reported
Naproxen	C	Unknown	Unk	Not Reported
Plaquenil	C	Unknown	1 Df (300 Mg), Qd	Not Reported
Tylenol With Codeine	C	Unknown	Unk	Not Reported
Aspirine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17402539	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200200407		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Otezla			S	Oral			Celgene
	Actemra			S	Unknown			Celgene
	Apo-Leflunomide			S	Unknown			Celgene
	Arava			S	Unknown			Celgene
	Cimzia			S	Subcutaneous			Celgene
	Cosentyx			S	Unknown			Celgene
	Enbrel			S	Unknown	50 Milligram		Celgene
	Hydroxychloroquine			S	Unknown			Celgene
	Hydroxychloroquine Sulfate			S	Unknown			Celgene
	Infliximab			S	Unknown			Celgene
	Leflunomide			S	Unknown			Celgene
	Methotrexate			S	Unknown	25 Milligram		Celgene
	Orencia			S	Unknown			Celgene
	Plaquenil			S	Unknown			Celgene
	Simponi			S	Subcutaneous			Celgene
	Sulfasalazine			S	Subcutaneous	50 Milligram		Celgene
	Acetaminophen			C	Unknown			Celgene
	Baclofen			C	Unknown	20 Milligram		Celgene
	Calcium			C	Unknown	500 Milligram		Celgene
	Dorzolamide Hydrochloride And Timolol Maleate			C	Ophthalmic			Celgene
	Ergocalciferol			C	Unknown			Celgene
	Ergocalciferol			C	Unknown			Celgene
	Estradiol			C	Unknown	.6 Percent		Celgene
	Estrogel			C	Unknown	.6 Percent		Celgene

Estrogel	C	Unknown			Celgene
Furosemide	C	Unknown	40 Milligram		Celgene
Gravol	C	Unknown			Celgene
Gravol Ginger	C	Unknown			Celgene
Levaquin	C	Unknown	50 Milligram		Celgene
Morphine	C	Unknown			Celgene
Potassium Chloride	C	Unknown	1500 Milligram		Celgene
Tofacitinib Citrate	C	Oral	10 Milligram		Celgene
Valsartan	C	Oral	320 Milligram		Celgene
Xalatan	C	Ophthalmic	50 Milligram		Celgene
Xeljanz	C	Oral	10 Milligram		Celgene
Zingiber Officinale	C	Oral	500 Milligram		Celgene

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17403018	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020059792		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Calcium Carbonate			S				Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Actemra			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S		Unk		Not Reported
	Asa			S		Unk		Not Reported
	Fosinopril			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Synthroid			S		Unk		Not Reported
	Tylenol [Paracetamol]			S		Unk		Not Reported

	Tylenol [Paracetamol]	S	Unknown	Unk		Not Reported
	Vitamin D [Colecalciferol]	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17403218	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020056477			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertension; Nausea; Thrombocytopenia; Vomiting	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Orencia			S				Not Reported
	Arava			S				Not Reported
	Gold			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17403272	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020052595			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Overdose; Psoriatic Arthropathy	Methotrexate Sodium			S	Unknown	25 G, Weekly		Pfizer
	Sulfasalazine			S	Unknown	1 G, 2x/Day		Pfizer
	Cosentyx			S	Unknown	300 Mg, Unk		Not Reported
	Cosentyx			S	Unknown	450 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, 1x/Day		Not Reported
	Leflunomide			C	Unknown	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17404196	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020054649			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug Hypersensitivity; Joint	Methotrexate Sodium			S	Unknown	Unk		Pfizer

Range Of Motion Decreased; Joint Swelling; Musculoskeletal Pain; Nausea; Periarthritis; Pruritus; Rheumatoid Arthritis	Sulfasalazine		S	Unknown	Unk	Pfizer
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Etanercept		C	Unknown	Unk	Not Reported
	Humira		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2020	17407178	DIRECT	Y	HO, LT			28 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoglycaemia; Seizure	Hydroxychloroquine			S		Other Frequency:First Dose;		Not Reported
	Metoprolol			C				Not Reported
	Carvedilol			C				Not Reported
	Vitamin B12			C				Not Reported
	Vitamin D			C				Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	11231180	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2015214504		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; Bone Erosion; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion	Enbrel			S	Unknown	50 Milligram, Qwk		Unknown
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Apo-Methotrexate			S	Subcutaneous	Unk		Not Reported
	Abatacept			S	Subcutaneous	125 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Thrombocytosis	Naprosyn	S	Unknown	500 Mg, 2x/Day	Not Reported
	Prednisone	S		Unk	Not Reported
	Prednisone	S		20 Mg, Daily	Not Reported
	Prednisone	S		2.5 Mg, Weekly	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Weekly	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	125 Mg, Weekly	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Naprelan	C		1000 Mg, 1x/Day	Not Reported
	Folic Acid	C		5 Mg, 3 Times/Wk	Not Reported
	Folic Acid	C	Unknown	5 Mg, 4 Times/Wk	Not Reported
	Folic Acid	C		5 Mg, Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Crestor	C		Unk	Not Reported
	Metoprolol	C		50 Mg, Unk	Not Reported
	Metoprolol	C	Unknown	Unk	Not Reported
	Gabapentin	C		Unk	Not Reported
	Lovastatin	C		Unk	Not Reported
	Vitamin D	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Tramadol Hydrochloride	C		Unk	Not Reported
	Naproxen	C	Unknown	500 Mg, 2x/Day	Not Reported
	Naproxen Sodium	C	Unknown	1000 Mg, Qd	Not Reported
	Rosuvastatin Calcium	C		Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Rosuvastatin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	12913938	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091776			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Intentional Product Use Issue; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	13571360	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017077269		61 YR	Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Rheumatoid Arthritis; Treatment Failure	Enbrel		S	Unknown	50 Milligram, Qwk	Amgen
	Methotrexate Sodium		S	Oral	25 Milligram, 1x/Day	Not Reported
	Methotrexate Sodium		S	Oral	25 Milligram, 1x/Day	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	200 Milligram, Qd	Not Reported
	Myochrysine		S	Intramuscular	25 Milligram, Qwk	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Gold		S	Unknown	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	14213267	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3758		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Remicade			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Cyclic		Not Reported
	Cimzia			S	Subcutaneous	Cyclical		Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Humira	S	Subcutaneous	Cyclic (Once Every 2 Weeks)	Not Reported
	Humira	S	Subcutaneous	Cyclical	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	14446503	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0985		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	2times/Wk		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

Xeljanz	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Celebrex	S	Oral	Not Reported
Celebrex	S	Unknown	Not Reported
Vioxx	S	Oral	Not Reported
Vioxx	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	14632688	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-020006		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Off Label Use; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Qd		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1500 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Anakinra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	15259069	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0134		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Vaginal	4 Times/Week		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown	4 Times/Week		Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Intolerance; Fibromyalgia; Herpes Zoster; Inappropriate Schedule Of Product Administration; Incorrect Route Of Product Administration; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	2 Times/Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Cyclic	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Cyclic	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Cyclic	Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported

Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S			Not Reported
Rituximab	S	Unknown		Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Day 1 &15	Not Reported
Ativan	C	Unknown		Not Reported
Cortisone	C	Intramuscular		Not Reported
Cortisone	C	Intra-articular		Not Reported
Darifenacin Hydrobromide	C	Unknown		Not Reported
Darifenacin Hydrobromide	C	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Benadryl	C	Unknown	As Necessary	Not Reported
Furosemide	C	Unknown		Not Reported
Loperamide	C	Unknown		Not Reported
Norflex	C	Unknown		Not Reported
Omnaris	C	Unknown		Not Reported
Pantoloc	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Vagifem	C	Vaginal		Not Reported
Leflunomide	C	Unknown		Not Reported
Abatacept	C	Unknown		Not Reported
Kineret	C	Unknown		Not Reported
Lasix	C	Unknown		Not Reported
Enablex	C	Unknown		Not Reported
Enablex	C	Unknown		Not Reported
Desoximetasone	C	Unknown		Not Reported

Acetaminophen	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Dexamethasone	C	Unknown	Not Reported
Darifenacin	C	Unknown	Not Reported
Dyclone	C	Unknown	Not Reported
Kenalog	C	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported
Plantago Ovata	C	Unknown	Not Reported
Dyclonine Hydrochloride	C	Unknown	Not Reported
Anakinra	C	Unknown	Not Reported
Laxisoft	C	Unknown	Not Reported
Pantoprazole Sodium	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Triamcinolone Acetonide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	15328824	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175343			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported

Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	15711487	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587408-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actonel			C				Not Reported

Alprazolam	C			Not Reported
Amlodipine	C	Oral		Not Reported
Acetylsalicylic Acid	C			Not Reported
Bisoprolol Fumarate	C			Not Reported
Celebrex	C			Not Reported
Ergocalciferol	C			Not Reported
Folic Acid	C			Not Reported
Metformin	C			Not Reported
Pantoprazole	C			Not Reported
Paroxetine	C			Not Reported
Prednisone	C			Not Reported
Risedronate	C			Not Reported
Simvastatin	C			Not Reported
Telmisartan	C			Not Reported
Xeljanz	C			Not Reported
Statex	C			Not Reported
Mtx	C			Not Reported
Morphine Sulphate	C			Not Reported
Asa	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	15838856	NON-EXPEDITED			US-PFIZER INC-2019013915		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	16073865	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2703788-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Orencia			S	Intravenous (not			Not Reported

Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased			otherwise specified)	
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Rituximab	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	16080945	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013872		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Bone Erosion; Contraindicated Product Administered; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Rosuvastatin			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported
	Cephalexin	C	Unknown	500 Milligram, Four Times/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	16689873	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-21418		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not	Unknown		Not Reported

			otherwise specified)		
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Cetirizine Hydrochloride	C	Unknown		Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Dexamethasone	C	Unknown	Unknown	Not Reported
	Gabapentin	C	Unknown		Not Reported
	Reactine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	16726516	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20181202738		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	16949982	EXPEDITED (15-DAY)		HO	NVSC2019DE011861			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Pulmonary Sepsis; Respiratory Failure; Septic Encephalopathy	Erelzi			S	Unknown	50 Mg, Qw		Novartis
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Not Reported

Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	20 Mg		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	250 Mg		Not Reported
Hydroxychloroquine	S	Unknown	250 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17360452	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000506			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Potassium Decreased; Rheumatoid Arthritis; Vitamin D Decreased	Hydroxychloroquine			S	Unknown	Unk; Tablet		Concordia
	Aubagio			S	Oral	14 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17405028	EXPEDITED (15-DAY)		OT	CA-ROCHE-1749484		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Peripheral Swelling; Rash; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17405412	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-008648			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Folic Acid	S	Unknown			Not Reported
	Fosamax	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17405500	EXPEDITED (15-DAY)		OT	CA-ROCHE-2545008			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal	Rivotril			S	Unknown			Not Reported
	Bisoprolol			S	Unknown			Not Reported
	Cefixime			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Nifedipine			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Zantac			S	Unknown			Not Reported
	Zopiclone			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17406023	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0777			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Asthma; Blister; Dyspepsia; Gastric Disorder; Oral Herpes; Oropharyngeal Pain; Pain In Extremity; Peripheral Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17406024	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0776			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Pancytopenia; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Infliximab			C	Unknown			Not Reported
	Infliximab			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17406028	EXPEDITED (15-DAY)		HO	CA-ROCHE-2542434			Female	CAN

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

Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Naproxen Sodium	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17406212	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541689		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility	Actemra			S	Unknown	Therapy Duration:- 366.0		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration:- 7.0 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration:- -59.0, 4 Months		Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Mobicox	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Diclofenac	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17406344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541854			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17406750	EXPEDITED (15-DAY)		DS	CA-ROCHE-2542981		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407002	EXPEDITED (15-DAY)		OT	SE-ACCORD-172239		59 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Dizziness; Ear Discomfort; Nausea; Tinnitus	Methotrexate			S		7 Tablets		Accord
	Plaquenil			S				Not Reported
	Prednisolone			C				Not Reported
	Methotrexate			S		6 Tablets		Accord
	Methotrexate			S		6 Tab. Methotrexate / V +5 Mg Prednisolone For Many Years		Accord
	Methotrexate			S		In November 2016 Mtx Was Increased To 8 Tab / V		Accord

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407019	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546720		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407151	EXPEDITED (15-DAY)		OT	CA-ROCHE-1698470		35 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disease Recurrence; Drug Ineffective; Infection; Insomnia; Joint Swelling; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To A General Medical Condition	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7.0 Months		Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	5.0 Months		Not Reported
	Gold			S	Unknown	7.0 Months		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407735	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543731			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Rabeprazole Sodium			C	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407796	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020056860		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Unknown			Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1 Every 12 Hours		Not Reported
	Prednisone			S	Oral	50 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	20 Mg, 1x/Day		Not Reported
	Immunoglobulin G Human			C	Intravenous (not otherwise specified)	Unk Unk, Monthly		Not Reported
	Immunoglobulin G Human			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17407906	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200201452			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Otezla			S	Oral			Celgene
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported

	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17408807	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17409234	EXPEDITED (15-DAY)		OT	NVSC2020CA037016			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Premature Baby	Calcium			S	Transplacental	Unk		Novartis
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Aspirin			S	Transplacental	162 Mg, Qd		Not Reported
	Enoxaparin			S	Transplacental	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17409348	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020060642			Female	CAN

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

Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Injury; Muscular Weakness; Nausea; Off Label Use; Treatment Failure; Vomiting	Methotrexate Sodium	S		25 Mg, Weekly	Pfizer
	Sulfasalazine	S		Unk	Pfizer
	Arava	S		20 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk (1 Every 2 Weeks)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, 1x/Day	Not Reported
	Orencia	S		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk, 1x/Day	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17410838	EXPEDITED (15-DAY)		OT	SE-PFIZER INC-2020062383		59 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Dizziness; Ear Discomfort; Nausea; Off Label Use; Product Use In Unapproved Indication; Tinnitus	Methotrexate Sodium			S		8 Df, Weekly (Mtx Was Raised To 8 Tab / Week)		Pfizer
	Methotrexate Sodium			S		6 Df, Unk		Pfizer
	Methotrexate Sodium			S		7 Df, Unk		Pfizer
	Methotrexate Sodium			S		6 Df, Weekly (Methotrexate / Week)		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Prednisolone			C		5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411055	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03977			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Infliximab			S	Unknown	Unknown		Not Reported

Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Certolizumab Pegol	S	Unknown	Unknown	Not Reported
	Golimumab	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Otezla	S	Unknown	Unknown	Not Reported
	Plaquenil	C	Unknown	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Unknown	Not Reported
	Ventolin Hfa	C	Unknown	Unknown Metered-Dose (Aerosol))	Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported
	Acetaminophen	C	Unknown	Unknown	Not Reported
	Advair	C	Unknown	Unknown	Not Reported
	Allopurinol	C	Unknown	Unknown	Not Reported
	Atrovent Hfa	C	Unknown	Unknown Metered-Dose (Aerosol)	Not Reported
	Codeine	C	Unknown	Unknown	Not Reported
	Cyclobenzaprine Hydrochloride	C	Unknown	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Unknown	Not Reported
	Ibuprofen	C	Unknown	Unknown	Not Reported
	Leucovorin Calcium	C	Unknown	Unknown	Not Reported
	Nexium Dr	C	Unknown	Unknown	Not Reported
	Dilaudid	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411060	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03965			Female	CAN

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

Drug Ineffective; Drug Intolerance; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver Function Test Increased; Skin Exfoliation	Etanercept		S	Unknown	Unknown	Not Reported
	Amlodipine Besilate		S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Leflunomide		S	Unknown	Unknown	Not Reported
	Methotrexate		S	Unknown	Unknown	Not Reported
	Naproxen		S	Unknown	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411068	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03811			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Large Intestine Infection	Etanercept			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411069	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03822			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported

Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Etanercept	S	Unknown	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Unknown	Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Leflunomide	S	Endocervical	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methylprednisolone	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Xeljanz	S	Unknown	Unknown	Not Reported
	Naproxen	C	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown	Unknown	Not Reported
	Rituxan	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411076	EXPEDITED (15-DAY)		HO	DE-SAMSUNG BIOEPIS-SB-2019-36506		83 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticular Perforation; Diverticulitis	Benepali			S	Subcutaneous			Not Reported
	Hcq			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411086	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03839			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Rheumatoid Arthritis	Etanercept			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Methotrexate			C	Unknown	Unknown		Not Reported
	Prednisone			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411089	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-03835		35 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unknown	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2020	17411442	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-006473			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Abnormal; Depression; Neuropathy Peripheral	Ramipril			S	Unknown	12.5 Milligram, Once A Day		Aurobindo
	Arava			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	12.5 Milligram, Once A Day		Not Reported
	Buprenorphine			S	Unknown	10 Microgram, Once A Day		Not Reported
	Calcium			S	Unknown	Unk		Not Reported
	Cyanocobalamin			S	Unknown	Unk		Not Reported
	Fish Oil			S	Unknown	Unk		Not Reported
	Lasix			S	Unknown	20 Milligram		Not Reported
	Magnesium Gluconate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	15 Milligram, Once A Day		Not Reported
	Pyridoxine Hydrochloride			S	Unknown	Unk		Not Reported
	Pyridoxine Hydrochloride			S	Unknown	Unk		Not Reported

Vitamin D	S	Unknown	Unk		Not Reported
Furosemide;Potassium Chloride	S	Unknown	20 Milligram		Not Reported
Magnesium	S	Unknown	Unk		Not Reported
Vitamin B6	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	11176748	EXPEDITED (15-DAY)		OT	CA-ROCHE-1589866		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Abnormal; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Response Decreased	Rituxan			S	Intravenous (not otherwise specified)	Discontinued After 2 Cycles, Therapy Duration: 4 Months.		Not Reported
	Humira			S	Subcutaneous	For 4 Years		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral	Therapy Duration: 4 Months		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 6 Months		Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	11214316	EXPEDITED (15-DAY)		OT	AU-ROCHE-1596702		52 YR	Female	AUS

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

Condition Aggravated; Skin Lesion; Treatment Failure	Mycophenolate Mofetil		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Prednisone		S	Unknown	For One Month	Not Reported
	Prednisone		S	Unknown	For More Than 3 Months	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	11610346	EXPEDITED (15-DAY)		HO	CA-ROCHE-1643242		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Decreased Immune Responsiveness; Lyme Disease	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	11688844	EXPEDITED (15-DAY)		OT	GB-ACCORD-034909		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Lethargy; Myelodysplastic Syndrome	Methotrexate			S	Unknown			Accord
	Metformin			S	Unknown			Accord
	Humira			S	Unknown	40 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	12919683	EXPEDITED (15-DAY)		OT	CA-ROCHE-1850264		56 YR	Female	CAN

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

Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Nausea; Off Label Use; Prescribed Overdose	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Naprosyn [Naproxen]	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	13190997	EXPEDITED (15-DAY)		HO	CA-ROCHE-1888707		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Neoplasm; Immune System Disorder; Lyme Disease	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	15275893	EXPEDITED (15-DAY)		OT	CA-ROCHE-2168133			Female	CAN

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

Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Minocycline	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Amoxil [Amoxicillin]	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Leflunomide	C	Unknown	Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	15298019	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20180803448		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug	Otezla			S	Oral			Celgene
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder; Sleep Disorder	Enbrel	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	10 Milligram	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Salazopyrin	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Minocycline	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Etanercept	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Minocin	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Oral	10 Milligram	Not Reported
	Ustekinumab	S	Unknown		Not Reported
	Methotrexate	C	Unknown	15 Milligram	Not Reported
	Abatacept	C	Unknown		Not Reported
	Orencia	C	Unknown	250 Milligrams	Not Reported

	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	15311145	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2016AP014163		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Off Label Use; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Naproxen			S	Oral	100 Mg, Qd		Apotex
	Naproxen			S	Oral	500 Mg, Bid		Apotex
	Naproxen			S	Oral	1000 Mg, Qd		Apotex
	Folic Acid			S	Unknown	5 Mg Twice In A Week		Not Reported
	Folic Acid			S	Unknown	400 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Bid		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Q.O.Wk.		Not Reported
	Folic Acid			S	Unknown	400 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Apo Folic Acid			S	Unknown	5 Mg, B.I.Wk.		Not Reported
	Hydroxychloroquine			S	Unknown	40 Mg, Unknown		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	40 Mg, Qd		Apotex
	Pantoprazole			S	Unknown	40 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Atenolol			S	Unknown	25 Mg, Qd		Apotex
	Sulfasalazin			S	Oral	500 Mg, Bid		Not Reported
	Sulfasalazin			S	Oral	1000 Mg, Bid		Not Reported
	Co Atenolol			S	Unknown	25 Mg, Qd		Not Reported
	Co Atenolol			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Q.Wk.		Not Reported

Methotrexate Sodium	S	Oral	25 Mg, Q.Wk.	Not Reported
Methotrexate Sodium	S	Oral	25 Mg, 1 Every 2 Weeks	Not Reported
Methotrexate Sodium	S	Oral	20 Mg, Q.O.Wk.	Not Reported
Palafer Cf	S	Unknown	Unk Unk, Qd	Not Reported
Pantoloc /01263204/	S	Unknown	40 Mg, Qd	Not Reported
Pantoloc /01263204/	S			Not Reported
Arava	S	Unknown	20 Mg, Qd	Not Reported
Arava	S	Oral	20 Mg, Qd	Not Reported
Naprosyn /00256201/	S	Oral	500 Mg, Bid	Not Reported
Naprosyn /00256201/	S	Oral	1000 Mg, Qd	Not Reported
Naprosyn /00256201/	S	Oral	100 Mg, Qd	Not Reported
Plaquenil /00072602/	S	Unknown	200 Mg, Bid	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Plaquenil /00072602/	S	Unknown	40 Mg, Qd	Not Reported
Enbrel	S	Subcutaneous	Unk, Unknown	Not Reported
Humira	S	Subcutaneous	Unk, Unknown	Not Reported
Orencia	S	Unknown	Unk,	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk, Unknown	Not Reported
Abatacept	S	Unknown	Unk, Unknown	Not Reported
Ascorbic Acid	S	Unknown	Unk, Unknown	Not Reported
Ascorbic Acid	S	Unknown	Unk, Qd	Not Reported
Ferrous Fumarate	S	Unknown	Unk, Unknown	Not Reported
Ferrous Fumarate W/Folic Acid	S	Unknown	Unk, Qd	Not Reported
Pantoprazole Sodium Sesquihydrate	S	Unknown	40 Mg, Qd	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Mg, Qd	Not Reported
Methotrexate	S	Oral	25 Mg, Q.Wk.	Not Reported

	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate	S	Oral	Unk Unk, Q.O.Wk.	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	20 Mg, Q.O.Wk.	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Palafer	S	Unknown	Unk	Not Reported
	Teva Pantoprazole	S	Unknown	40 Mg, Qd	Not Reported
	Vitamin C /00008001/	S	Unknown	Unk, Qd	Not Reported
	Celebrex	C	Oral	200 Mg, Qd	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Prednisone	C	Intracardiac	5 Mg, Qd	Not Reported
	Prednisone	C	Unknown	Unk Unk, Q.O.Wk.	Not Reported
	Celecoxib	C	Oral	200 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	15394598	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184764		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Imuran [Azathioprine]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	15730589	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20181202419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	15930195	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2654210-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16093680	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2709127-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Levothyroxine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16388002	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029948			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Celecoxib Capsules			S	Unknown	200 Milligram, Once A Day		Aurobindo
	Citalopram			S	Unknown	20 Milligram, Once A Day		Aurobindo
	Sertraline			S	Unknown	25 Milligram		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Indomethacin			S	Unknown	50 Milligram, 3 Times A Day		Not Reported
	Indomethacin			S				Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Oral	10 Milligram		Not Reported
	Temazepam			S	Unknown	Unk		Not Reported
	Toradol			S	Intramuscular	10 Milligram		Not Reported
	Toradol			S				Not Reported
	Zopiclone			S	Unknown	7.5 Milligram		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Lidocaine			C	Unknown	Unk		Not Reported
	Methylprednisolone Acetate			C	Unknown	80 Milligram		Not Reported
	Naproxen			C	Unknown	500 Milligram, Two Times A Day		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Vitamin D			C	Unknown	50000 International Unit,		Not Reported

Every Week

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16413232	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044080		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Drug Ineffective; Incorrect Route Of Product Administration; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported

	Tofacitinib Citrate		S	Unknown	Not Reported
	Kevzara		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16586116	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557146-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Infection; Pneumonia; Pneumonia; Synovitis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16714551	EXPEDITED (15-DAY)		OT	PHHY2019DE188505			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Ramipril			S	Oral	1 Df, Qd (1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval		Not Reported
	Omeprazole			S	Oral	1 Df, Qd (1 Df, 2x/Day (1 - 0 - 1))		Novartis
	Pregabalin			S	Unknown	3 Df, Qd		Not Reported
	Apixaban			S	Unknown	2 Df (1 Dosage Form, Bid (1-0-1))		Not Reported
	Apixaban			S	Unknown	5 Mg, Qd (2.5 Milligram, Bid)		Not Reported
	Sildenafil Citrate			S	Unknown	60 Mg, Qd		Not Reported
	Quensyl			S	Unknown	2 Df, Qd (1 Df, Bid (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval)		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd (Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv		Not Reported
	Spasmolyt			S	Unknown	1 Df, Qd		Not Reported
	Eliquis			S	Unknown	2 Df, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Roactemra			S	Unknown	162 Mg, Qw		Not Reported
	Volibris			S	Oral	30 Mg, Qd		Not Reported
	Volibris			S	Oral	1 Df, Qd		Not Reported
	Lyrica			S	Unknown	300 Mg, Qd (100		Not Reported

Milligram, Tid)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16716102	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20190803947			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Blood Cholesterol Increased; Bone Erosion; Bronchitis; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Hypertension; Infection; Joint Dislocation; Joint Stiffness; Malaise; Nasopharyngitis; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Psoriasis; Synovitis; Tachycardia; Upper Respiratory Tract Infection	Otezla			S	Oral			Celgene
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Telmisartan			S	Unknown			Not Reported
	Zopiclone			S	Unknown			Not Reported
	Amlodipine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Cosentyx			S	Unknown			Not Reported

	Amitriptyline	C	Oral	Not Reported
	Betamethasone	C	Topical	Not Reported
	Betamethasone Dipropionate W/Calcipotriol	C	Unknown	Not Reported
	Melatonin	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	16716446	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20190803878		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Liver Function Test Increased; Palpitations; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure	Otezla			S	Oral			Celgene
	Cosentyx			S	Subcutaneous	300 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous drip	600 Milligram		Not Reported
	Infliximab			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram		Not Reported
	Methotrexate			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Oral	15 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported
	Sulfasalazine			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
Hydrochlorothiazide	S	Oral	25 Milligram	Not Reported
Clonidine Hydrochloride	C	Oral		Not Reported
Esomeprazole Magnesium Trihydrate	C	Oral	40 Milligram	Not Reported
Fluticasone Propionate	C	Unknown		Not Reported
Gabapentin	C	Oral	2000 Milligram	Not Reported
Folinic Acid	C	Unknown		Not Reported
Folic Acid	C	Unknown	5 Milligram	Not Reported
Losartan	C	Unknown		Not Reported
Metoprolol Tartrate	C	Oral	100 Milligram	Not Reported
Mometasone Furoate	C	Nasal	50 Microgram	Not Reported
Naproxen	C	Unknown		Not Reported
Plaquenil	C	Unknown	300 Milligram	Not Reported
Acetaminophen And Codeine	C	Oral	325 Milligram	Not Reported
Amitriptyline Hydrochloride	C	Oral	50 Milligram	Not Reported
Aspirin	C	Unknown	81 Milligram	Not Reported
Baclofen	C	Unknown	20 Milligram	Not Reported
Betahistine Hydrochloride	C	Oral	16 Milligram	Not Reported
Caffeine	C	Oral		Not Reported
Calcium	C	Unknown	1000 Milligram	Not Reported
Clonidine	C	Unknown		Not Reported
Amoxicillin Trihydrate/Clarithromycin/Esomeprazole Magnesium Trihydrat	C	Unknown		Not Reported
Acetaminophen	C	Oral		Not Reported
Acetaminophen	C	Unknown	325 Milligram	Not Reported
Codeine	C	Oral		Not Reported
Codeine	C	Unknown	325 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17218862	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019548324		76 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Application Site Erythema; Drug Ineffective; Hypoacusis; Off Label Use; Product Use Issue; Psoriatic Arthropathy	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, Daily (Qd)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral	400 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17395434	EXPEDITED (15-DAY)		HO	BR-STRIDES ARCOLAB LIMITED-2020SP001169		32 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dental Caries; Dental Necrosis; Off Label Use; Tooth Abscess; Tooth Fracture; Toothache	Tacrolimus			S	Unknown	2 Milligram Per Day		Strides
	Prednisolone			S	Unknown	5 Milligram Per Day		Not Reported
	Alendronate			S	Oral	70 Milligram, Once A Week		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Per Day		Not Reported
	Tamoxifen			C	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411606	EXPEDITED (15-DAY)		DS	CA-ROCHE-2540641		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported

Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Adalimumab	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous	4.0 Years	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	404.0 Days	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Infliximab	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous	5.0 Years	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411609	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-235348		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Gastroenteritis Cryptosporidial; Hypogammaglobulinaemia; Tachycardia	Methotrexate			S	Unknown			Sun
	Hydroxychloroquine			S	Unknown			Sun
	Mycophenolate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411672	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542957		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Lyrica			C				Not Reported
	Marijuana			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Oxycodone			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411767	EXPEDITED (15-DAY)		HO	CA-ROCHE-2539868			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Onychomycosis	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Xeljanz		S	Unknown	Not Reported
	Arava		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411790	EXPEDITED (15-DAY)		DS	CA-ABBVIE-20K-028-3270161-00		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Influenza; Injection Site Pain; Pain; Rheumatoid Arthritis; Skin Burning Sensation; Skin Exfoliation	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Allopurinol			C				Not Reported
	Hydromorph Contin			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546716		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Actemra	C	Unknown	Not Reported
	Bifidobacterium Bifidum	C		Not Reported
	Celebrex	C		Not Reported
	Loperamide	C		Not Reported
	Methotrexate	C		Not Reported
	Pantoprazole	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411845	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543626			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17411893	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0796			Male	CAN

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

Drug Ineffective; Overdose; Psoriatic Arthropathy	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412024	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0799			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypertension; Nausea; Thrombocytopenia; Vomiting	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412049	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0803			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug Hypersensitivity; Joint Range Of Motion Decreased; Joint Swelling; Musculoskeletal Pain;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Nausea; Periarthritis; Pruritus; Rheumatoid Arthritis	Leflunomide	S	Unknown	Not Reported
	Etanercept	C	Unknown	Not Reported
	Humira	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412097	EXPEDITED (15-DAY)		HO	US-ZYDUS-047509		94 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Cardiac Event; Dizziness	Hydroxychloroquine			S	Oral			Zydus Pharm
	Albuterol			C	Unknown			Not Reported
	Apixaban			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Vitamin D			C	Unknown			Not Reported
	Carvedilol			C	Unknown			Not Reported
	Loratadine			C	Unknown			Not Reported
	Erythromycin			C	Unknown			Not Reported
	Fluticasone			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Isosorbide			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Warfarin			C	Unknown			Not Reported
	Clopidogrel			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412105	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540711			Female	CAN

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

Administered; Drug Ineffective; Rheumatoid Arthritis	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412152	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546734		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412232	EXPEDITED (15-DAY)		OT	SE-TEVA-2020-SE-1184606		59 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deafness Neurosensory; Dizziness; Ear Discomfort; Nausea; Tinnitus	Methotrexate			S	Unknown	"Nov 2016, Mtx Was Raised To 8 Tab/V".		Barr
	Methotrexate			S	Unknown	7 Tablets		Barr
	Methotrexate			S	Unknown	6 Tablets		Barr
	Methotrexate			S	Unknown	"6 Tab. Methotrexat/V +5 Mg Prednisolon For Many Years".		Barr
	Plaquenil			S	Unknown			Not Reported
	Prednisolone			C		5mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412298	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3270872-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Impaired Work Ability; Joint Stiffness; Mobility Decreased; Muscular Weakness; Musculoskeletal Stiffness; Nausea; Ototoxicity; Pain In Extremity; Spinal Pain; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412387	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540889			Female	CAN

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

Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Actemra	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412439	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540929			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Endocervical			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Synthroid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Meloxicam			C				Not Reported

	Acetaminophen;Codeine Phosphate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412591	EXPEDITED (15-DAY)		HO	CA-ROCHE-1866268		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17412841	EXPEDITED (15-DAY)		CA, HO, OT	GR-LUPIN PHARMACEUTICALS INC.-2020-00745			Male	GRC

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

Aorta Hypoplasia; Bradycardia Foetal; Congenital Aortic Stenosis; Echocardiogram Abnormal; Foetal Exposure During Pregnancy; Heart Block Congenital; Neonatal Respiratory Distress; Ventricular Septal Defect	Hydroxychloroquine	S	Transplacental	Unk		Lupin
	Acetylsalicylic Acid	S	Transplacental			Not Reported
	Prednisolone	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413195	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546739			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413199	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546743		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Bite; Drug Ineffective; Emotional	Actemra			S	Unknown			Not Reported

Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituxan	S	Intravenous drip	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Restasis	C	Oral	Not Reported
	Sulfasalazine	C	Oral	Not Reported
	Synthroid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413260	EXPEDITED (15-DAY)		OT	CA-SA-2020SA036521			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Topicort			S				Sanofi
	Alendronate Sodium			S				Not Reported
	Arava			S				Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Methotrexate			S				Not Reported
	Folic Acid			S	Subcutaneous	1 Mg		Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S	Topical			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413267	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543709			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413280	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543697		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Ergocalciferol	C	Unknown	Not Reported
	Folinic Acid	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413281	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543642			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413326	EXPEDITED (15-DAY)		HO	CA-ROCHE-2546133			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Arava	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Viread	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413355	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543703			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413693	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546111			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Sulfasalazine	S	Unknown		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413707	EXPEDITED (15-DAY)		HO, OT	IN-MYLANLABS-2020M1016074		41 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Infection; Brain Abscess; Drug Ineffective; Hydrocephalus; Nocardiosis; Septic Shock; Shunt Infection	Methotrexate			S	Unknown	10 Milligram, Qw		Not Reported
	Meropenem			S	Intravenous (not otherwise specified)			Not Reported
	Meropenem			S				Not Reported
	Prednisolone			S	Unknown	30 Milligram, Qd		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Mylan
	Trimethoprim Sulfamethoxazole			S	Intravenous (not otherwise specified)	15 Mg/Kg Of Trimethoprim Divided In Three Doses		Mylan
	Trimethoprim Sulfamethoxazole			S				Mylan
	Amikacin			S	Intravenous (not otherwise specified)	7.5 Milligram/Kilogram		Mylan
	Amikacin			S				Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413936	EXPEDITED (15-DAY)		OT	CA-BAXTER-2020BAX002879			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)	Dosage Form- Not Specified		Baxter
	Arava			S	Unknown	Dosage Form- Tablets		Not Reported
	Azithromycin			S	Unknown	Dosage Form- Not Specified		Not Reported
	Azithromycin			S	Unknown	Dosage Form- Not		Not Reported

			Specified	
Benadryl	S	Unknown	Dosage Form- Not Specified	Not Reported
Celebrex	S	Oral		Not Reported
Cimzia	S	Subcutaneous	Dosage Form- Solution Subcutaneous Single-Use Prefilled Syringe	Not Reported
Demerol	S	Unknown	Dosage Form- Not Specified	Not Reported
Enbrel	S	Unknown		Not Reported
Humira	S	Subcutaneous	Dosage Form- Solution Subcutaneous	Not Reported
Imuran	S	Unknown	Dosage Form- Not Specified	Not Reported
Levofloxacin	S	Unknown	Dosage Form- Not Specified	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown	Dosage Form Not Specified	Not Reported
Plaquenil	S	Unknown	Dosage Form- Tablets	Not Reported
Simponi	S	Subcutaneous	Dosage Form- Solution Subcutaneous	Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Ezetrol	C	Unknown	Dosage Form- Tablets	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413946	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2020M1017169		40 YR	Female	CAN

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

Maternal Exposure During Pregnancy; Retinal Toxicity	Hydroxychloroquine		S	Unknown	Later, Restarted At The Time Of Pregnancy Until 26weeks Of Gestational	Not Reported
	Azathioprine		S	Unknown	Initial Dosage Not Stated. Later, At The Time Of Pregnancy She Was Maintained On150 Mg Daily.	Not Reported
	Azathioprine		S	Unknown	150 Milligram, Qd	Not Reported
	Azathioprine		S	Unknown	175 Milligram, Qd	Not Reported
	Nifedipine		S	Unknown	30 Milligram, Bid	Not Reported
	Prednisone		S	Unknown	5 Milligram, Qd	Mylan
	Prednisone		S	Unknown	40 Milligram, Qd	Mylan
	Acetylsalicylic Acid		S	Unknown	162 Milligram, Qd	Mylan
	Methylprednisolone		C	Intravenous (not otherwise specified)	1 Gram	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17413953	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546719			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17414259	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020058166		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Balance Disorder; Cardiac Disorder; Dermatitis Allergic; Drug Hypersensitivity; Foot Deformity; Hand Deformity; Infection; Irritable Bowel Syndrome; Lung Neoplasm Malignant; Pain In Extremity; Therapeutic Product Effect Decreased; Toe Amputation	Methotrexate Sodium			S	Oral	10 Mg, Unk		Pfizer
	Arava			S		Unk		Not Reported
	Gold			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil S			S		Unk		Not Reported
	Arnica Montana			C		Unk		Not Reported
	Asa			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415069	EXPEDITED (15-DAY)		OT	CA-ROCHE-2546744		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration 184.0		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Therapy Duration 0.0		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration 3.0 Years		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Therapy Duration 7.0 Months		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Etanercept			S	Unknown	Therapy Duration 31.0		Not Reported

	Arava	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415209	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020058429		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adrenal Disorder; Amnesia; Arthralgia; Asthma; Blood Pressure Increased; Bronchitis; Burning Sensation; Cough; Diarrhoea; Dysgeusia; Dyspnoea; Emotional Distress; Emphysema; Fatigue; Furuncle; Genital Herpes Simplex; Head Injury; Headache; Herpes Virus Infection; Hypertension; Inflammation; Injection Site Erythema; Injection Site Induration; Injection Site Inflammation; Injection Site Pruritus; Insomnia; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Respiratory Failure; Rhinorrhoea; Secretion Discharge; Sleep Disorder; Urine Odour Abnormal; Weight Increased	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Quetiapine Fumarate			S	Unknown			Not Reported
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported
	Alendronate Sodium			C				Not Reported
	Amlodipine			C				Not Reported
	Ativan			C	Unknown	Unk Unk, As Needed		Not Reported
	Lipitor			C				Not Reported
	Methadone			C	Oral	10 Mg, 1x/Day		Not Reported
	Pantoloc [Pantoprazole]			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Valtrex			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415269	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183886			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415270	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184218		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Swelling; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Sulfasalazine			C	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415271	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183917			Female	CAN

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

Gastrointestinal Toxicity; Hepatotoxicity	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415275	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1184182			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Fall; Gait Disturbance; Mobility Decreased; Peripheral Swelling; Therapeutic Response Decreased	Leflunomide			S	Unknown			Barr
	Arava			S	Oral	200 Milligram Daily;		Not Reported
	Lovenox			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415297	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA032797		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Neuropathy Peripheral; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Sleep Disorder; Spinal Stenosis	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Novartis
	Aclasta			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetaminofen Tramadol			S	Oral	Unk		Not Reported
	Arava			S	Unknown	20 Mg		Not Reported
	Actonel			C	Unknown	Unk		Not Reported

Enbrel	S	Unknown	Unk		Not Reported
Humira	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Plaquenil	S	Unknown	400 Mg, Qd		Not Reported
Sulfasalazine	S	Unknown	2 G, Qd		Not Reported
Calcium	C	Unknown	Unk		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported
Lorazepam	C	Unknown	Unk		Not Reported
Lyrica	C	Unknown	Unk		Not Reported
Metformin	C	Unknown	Unk		Not Reported
Methylprednisolone Acetate	C	Unknown	Unk		Not Reported
Nortriptyline	C	Unknown	Unk		Not Reported
Nortriptyline Hydrochloride	C	Unknown	Unk		Not Reported
Premarin	C	Unknown	Unk		Not Reported
Tylenol 8 Hr Arthritis Pain	C	Unknown	Unk		Not Reported
Vagifem	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415389	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183894			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Malaise; Nausea; Retinal Toxicity; Vomiting	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Azathioprine			C	Oral	100 Milligram Daily;		Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Feb-2020	17415556	EXPEDITED (15-DAY)		CA, OT	NVSC2020GR035293			Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia Foetal; Foetal Exposure During Pregnancy; Heart Disease Congenital; Respiratory Distress	Acetylsalicylic Acid			S	Unknown	Unk, (Maternal Dose: Unk)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, (Maternal Dose: Unk)		Novartis
	Prednisolone			S	Unknown	Unk, (Maternal Dose: Unk)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	11278460	EXPEDITED (15-DAY)		OT	CA-ROCHE-1606928		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Rheumatoid Arthritis; Synovitis; Vomiting	Rituxan			S	Intravenous (not otherwise specified)	1 Gm. 1/2		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	20-25 Mg, Therapy Duration: 6 Years		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Orencia	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Celebrex	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	11752885	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2015121181		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Blood Pressure Fluctuation; Body Temperature Decreased; Bone Density Abnormal; Chills; Cough; Deafness; Decreased Appetite; Disability; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypercholesterolaemia; Infection; Insomnia; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Oropharyngeal Pain; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Rosacea; Somnolence; Stress;	Enbrel			S	Subcutaneous	Unk		Amgen
	Prednisone			S	Oral	25 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	50 Milligram		Not Reported
	Prednisone			S	Oral	3 Milligram, Qd		Not Reported
	Prednisone			S	Oral	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qd		Not Reported
	Indocid			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Vomiting; Weight Increased			otherwise specified)		
	Indomethacin	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	480 Milligram, Cyclical	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Gold (198 Au)	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	50 Milligram	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Qd	Not Reported
	Apo-Prednisone	S	Oral	25 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25,Unk, Qd	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk (Single Use Prefilled Syringe)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Indometacin	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Acetaminophen	S	Oral	650 Milligram	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	S	Oral	50 Milligram	Not Reported
	Methylprednisolone Sodium Succinate	S	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Oral	Unk Unk, Bid	Not Reported
	Folic Acid	C	Oral	Unk, Qwk	Not Reported
	Folic Acid	C	Oral	5 Milligram, Unk	Not Reported

	Cymbalta	C	Oral	30 Milligram, 30 Mg, Qd At Nights	Not Reported
	B Complex [Vitamin B Complex]	C		Unk	Not Reported
	Ciprodex [Ciprofloxacin Lactate]	C		Unk	Not Reported
	Fish Oil	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	12212678	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016036511		76 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthritis; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder; Joint Swelling; Lung Disorder; Musculoskeletal Pain; Peripheral Swelling; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Vascular Graft	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	20 Milligram, Cyclical		Not Reported
	Arava			S	Unknown	10 Milligram, Cyclical		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	1000 Milligram, Bid		Not Reported
	Plaquenil			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			S	Unknown	1 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	5 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Lax-A-Day	C		Unk, Occ	Not Reported
Vitamin B12	C	Sublingual	1200 Microgram, Qd	Not Reported
Endocet	C		5+325 Mg, 1 Tablet 2 Times Per Day Prn	Not Reported
Endocet	C		1 Dose 2 Every 1 Day	Not Reported
Indomethacin	C		Unk	Not Reported
Pennsaid	C		Unk	Not Reported
Oxycocet	C		2 Tabs, 4-5x/Week	Not Reported
Asa	C		325 Milligram, Occ	Not Reported
Naprelan	C		1000 Milligram, Cyclical	Not Reported
Metoprolol	C		75 Milligram, Bid	Not Reported
Folic Acid	C		5 Milligram, Cyclical	Not Reported
Bisoprolol	C		5 Milligram, Qd	Not Reported
Omega 3	C		12000 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	12337536	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016055447		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Ergocalciferol	C	Unknown	Unk		Not Reported
Leucovorin	C		Unk		Not Reported
Prednisone	C		Unk		Not Reported
Apo-Hydroxyquine	C		Unk		Not Reported
Calcium	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	13161522	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-2016047597		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Enthesopathy; Erythema;	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S	Oral			Celgene
	Otezla			S	Oral	120 Milligram		Celgene
	Otezla			S	Oral			Celgene
	Otezla			S	Oral			Celgene
	Adalimumab			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral	.6 Milligram		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported

Erythema; Erythema; Fatigue; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Hypersensitivity; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Pain; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Etanercept	S	Unknown		Not Reported
	Golimumab	S	Subcutaneous		Not Reported
	Infliximab	S	Intravenous drip	400 Milligram	Not Reported
	Sulfasalazine	S	Endocervical		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ustekinumab	S	Subcutaneous		Not Reported
	Ustekinumab	S	Unknown		Not Reported
	Abatacept	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	6 Dosage Forms	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported
	Motrin	S	Oral		Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram	Not Reported
	Arava	S	Unknown	20 Milligram	Not Reported

Celebrex	S	Oral	200 Milligram	Not Reported
Codeine	S	Unknown		Not Reported
Cosentyx	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Remicade	S	Intravenous drip		Not Reported
Rituximab	S	Intravenous drip	2000 Milligram	Not Reported
Rituximab	S	Unknown		Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Methotrexate	S	Oral		Not Reported
Apo Ibuprofen	S	Oral		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Colchicine	C	Oral	.6 Milligram	Not Reported
Folic Acid	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Methotrexate Sodium	C	Oral	4.0 Dosage Forms	Not Reported
Methotrexate Sodium	C	Unknown	10 Milligram	Not Reported
Methotrexate Sodium	C	Oral		Not Reported
Methotrexate Sodium	C	Unknown	2.5 Milligram	Not Reported
Mogadon	C	Unknown	5 Milligram	Not Reported
Oxyneo	C	Oral	40 Milligram Er	Not Reported
Oxyneo	C	Oral	10 Milligram	Not Reported
Oxyneo	C	Unknown	40 Milligram Er	Not Reported
Oxyneo	C	Unknown	10 Milligram	Not Reported
Oxyneo	C	Unknown	10 Milligram	Not Reported
Uloric	C	Oral	160 Milligram	Not Reported
Uloric	C	Oral	80 Milligram	Not Reported
Uloric	C	Unknown	80 Milligram	Not Reported
Uloric	C	Unknown		Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported

Oxycodone Hydrochloride	C	Unknown	10 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown		Not Reported
Febuxostat	C	Unknown	160 Milligram	Not Reported
Nitrazepam	C	Unknown		Not Reported
Nitrazepam	C	Unknown		Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Nitrazepam	C	Unknown		Not Reported
Dexilant	C	Unknown		Not Reported
Gravol	C	Unknown		Not Reported
Benadryl	C	Unknown		Not Reported
Acide Folique	C	Unknown		Not Reported
Actonel	C	Oral	35 Milligram	Not Reported
Naproxen	C	Unknown	500 Milligram	Not Reported
Oxycodone	C	Unknown	10 Milligram	Not Reported
Oxycodone	C	Unknown	40 Milligram	Not Reported
Oxycodone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Vitamin D3	C	Oral	2000 Iu (International Unit)	Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	13348182	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017039391		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported

	Actemra	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Triatec	C		Unk	Not Reported
	Atasol	C		Unk	Not Reported
	Tylenol	C	Unknown	650 Mg, Bid	Not Reported
	Atacand	C	Unknown	Unk	Not Reported
	Hydrodiuril	C		Unk	Not Reported
	Vitamin D	C		Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Premarin	C		Unk	Not Reported
	Neurontin	C		600 Mg, Tid	Not Reported
	Acetaminophen	C		650 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	13782530	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017103905		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk Unk, Qwk		Not Reported

Morphine	C	Topical	Unk, Every Two Days		Not Reported
Erythromycin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	14187184	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170219			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Varenicline Tartrate			S	Oral	Unk Unk, Qd		Not Reported
	Varenicline Tartrate			S	Oral	1 Dosage Form, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			C	Unknown	Unk		Not Reported

	Valtrex	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Rosuvastatin Calcium	C	Unknown	Unk	Not Reported
	Esomeprazole Magnesium W/Naproxen	C	Unknown	Unk	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Unk	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Naproxen	C		Unk	Not Reported
	Oxycodone Hydrochloride	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	14246850	EXPEDITED (15-DAY)		HO	CA-ROCHE-2028708		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported

Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Hydroxychloroquine	S	Unknown	Not Reported
	Myochrysine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisolone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	15291603	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20180803571		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S	Oral			Celgene
	Otezla			S	Oral			Celgene
	Otezla			S	Oral			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cosentyx			S	Unknown	300 Milligram		Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Infliximab			S	Intravenous drip	500 Milligram		Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	.6 Milliliter		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Pencillin (Benzyl Penicillin)			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	15399793	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083448			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	15635328	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105928			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Exostosis; Foot Deformity;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Minocycline	S	Unknown		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Morphine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Wellbutrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	15842727	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016021061		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported

Intolerance; Fatigue; Hepatic Enzyme Increased; Nausea; No Adverse Event; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure; Vomiting	Methotrexate	S	Subcutaneous	20 Milligram, Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Unk	Not Reported
	Methotrexate	S	Unknown	Unk Unk, Qd	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Milligram, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Ciclosporin	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Neoral	S	Subcutaneous	Unk	Not Reported
	Neoral	S	Oral	Unk	Not Reported
	Neoral	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Milligram	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Unk	Not Reported

Orencia	S	Subcutaneous	12.5 Milligram, Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Xeljanz Xr	C		Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk, Qd	Not Reported
Xeljanz	S	Oral	10 Milligram, Qd	Not Reported
Xeljanz	S	Unknown	Unk Unk, Qd	Not Reported
Methotrexate Sodium	S	Subcutaneous	20 Milligram	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	8 Milligram, Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	15866486	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1094		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Naroxin			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Risedronate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

	Methotrexate Sodium			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	16636557	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN014720		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use	Desloratadine			S	Unknown	5 Mg		Merck
	Singulair			S	Unknown	10 Mg. Dosage Form: Not Specified		Merck
	Apo Prednisone			S	Unknown	Unk		Not Reported
	Apo Ranitidine			S	Unknown	150.0 Mg, 2 Every 1 Day		Not Reported
	Cetirizine Hydrochloride			S	Unknown	20.0 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Not Reported
	Ketotifen Fumarate			S	Unknown	4.0 Mg, 2 Every 1 Days		Not Reported
	Cromolyn Sodium			S	Unknown	200 Mg, 3 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17352131	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1175498		47 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antisynthetase Syndrome; Rebound Effect	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17417570	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-236079		32 YR	Male	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis; Dental Necrosis; Tooth Abscess	Alendronic Acid			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Prednisone			S	Unknown	Unk		Mutual

	Tacrolimus	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17417741	EXPEDITED (15-DAY)		HO	CA-ROCHE-2547886		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17417966	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184031		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported
	Depo-Medrol	C	Intra-articular	80 Milligram Daily;	Not Reported
	Diclofenac	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418219	EXPEDITED (15-DAY)		HO	US-ZYDUS-047474		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastroenteritis Cryptosporidial; Hypogammaglobulinaemia; Leukopenia; Neutropenia	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Mycophenolic Acid			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418399	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543618		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty	Actemra			S	Unknown			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Infliximab	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Desoximetasone	C		Not Reported
Methotrexate	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418405	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543745		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418434	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543742			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Celebrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418479	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543690		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown	4.0 Months		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543627		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous	Therapy Duration:- 5.0 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration:- 11.0 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418616	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0811		61 YR	Female	CAN

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

Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Calcium Carbonate	S	Unknown	Not Reported
	Morphine Sulfate	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Asa	S	Unknown	Not Reported
	Fosinopril	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Synthroid	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported
	Vitamin D	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418650	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184235		70 YR	Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418682	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1184190		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous	1.4286 Milligram Daily;		Barr
	Methotrexate			S	Unknown	1.7857 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	2.1429 Milligram Daily;		Barr
	Methotrexate			S	Unknown	1.4286 Milligram Daily;		Barr
	Methotrexate			S	Unknown	1.7143 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	2.5 Milligram Daily;		Barr
	Methotrexate			S	Unknown	1.7143 Milligram Daily;		Barr
	Methotrexate			S	Unknown	1.4286 Milligram Daily;		Barr
	Alendronate Sodium			S	Unknown	10 Milligram Daily;		Actavis
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	12 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine/00072603/			S	Unknown			Not Reported
	Methotrexate			S	Oral	1.4286 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418684	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1184211			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418688	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183936		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	2.1429 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418705	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183932		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule;	Leflunomide			S	Unknown	1 Dosage Forms Daily;		Barr

Rheumatoid Arthritis	Methotrexate		S	Subcutaneous		Barr
	Risedronate Sodium		S	Unknown	5 Milligram Daily;	Teva
	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	1 Dosage Forms Daily;	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418744	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0844		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective; Off Label Use; Product Use In Unapproved Indication	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Immunoglobulin G Human			C	Unknown			Not Reported
	Immunoglobulin G Human			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418787	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0827			Female	CAN

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

Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Injury; Muscular Weakness; Nausea; Off Label Use; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418909	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3275098-00		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Disorder; Drug Ineffective; Head Injury; Rheumatoid Arthritis; Synovitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17418955	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543692		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Hydroxychloroquine		S	Oral	Not Reported
	Methotrexate		S	Oral	Not Reported
	Sulfasalazine		S	Intravenous (not otherwise specified)	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Restasis		C	Unknown	Not Reported
	Synthroid		C	Unknown	Not Reported
	Xeljanz		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419040	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1183361		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Pollakiuria; Product Dose Omission	Leucovorin			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419072	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007699		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Retinal Toxicity	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Mycophenolate			S	Unknown	1 G, Bid		Novartis

	Methylprednisolone	C	Intravenous (not otherwise specified)	1 G, (For 2 Days)	Not Reported
	Prednisone	C	Unknown		Not Reported
	Azathioprine	C	Unknown	100 Mg, Qd	Not Reported
	Cyclophosphamide	C	Intravenous (not otherwise specified)	500 Mg, Every Two Weeks For Six Doses	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419141	EXPEDITED (15-DAY)		DS	CA-ROCHE-2543637		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported

	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz		S	Oral	Not Reported
	Xeljanz		S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419152	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183879		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Mefenamic Acid			C	Unknown			Not Reported
	Prednisone			C	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Oral	6 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419155	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1183858		52 YR	Female	CAN

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

Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Cefazolin	S	Unknown		Not Reported
	Leflunomide	S	Oral		Barr
	Methotrexate	S	Subcutaneous	3.5714 Milligram Daily;	Barr
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Naproxen	C	Unknown	1000 Milligram Daily;	Not Reported
	Viread	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419158	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543730		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Orencia	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Actonel	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419171	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2020-CA-1184234		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Leflunomide			S				Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S				Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S		Not Reported
Gold	S	Subcutaneous	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S		Not Reported
Sodium Aurothiomalate	S		Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S		Not Reported
Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
Cannabis Sativa	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Rituximab	C	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419181	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543711			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Caffeine			C	Unknown			Not Reported

Codeine	C	Unknown	Not Reported
Dorzolamide Hydrochloride	C	Ophthalmic	Not Reported
Folic Acid	C	Unknown	Not Reported
Levothyroxine	C	Unknown	Not Reported
Meprobamate	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Ramipril	C	Unknown	Not Reported
Timolol Maleate	C	Ophthalmic	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419243	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183915		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxyquinoline Sulfate			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rapamune			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Oral			Not Reported
	Tacrolimus			S	Oral			Not Reported

	Imuran		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419259	EXPEDITED (15-DAY)		DS	CA-ROCHE-2543752			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419385	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184192		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Disorder; Liver Injury	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419404	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184227			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419406	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1184201		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Indometacin			S	Unknown			Actavis
	Prednisone			S	Oral	25 Milligram Daily;		Actavis
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Cymbalta			C	Oral	30 Milligram Daily;		Not Reported
	Folic Acid			C	Oral			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419417	EXPEDITED (15-DAY)		OT	IN-JNJFOC-20200210530			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Meconium Aspiration Syndrome; Pneumonia Aspiration; Pulmonary Arterial Hypertension; Respiratory Distress	Cetirizine Hydrochloride			S	Transplacental	10 Milligram, 2x/Day (Bid)		Not Reported
	Prednisolone			S	Transplacental	5 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine			S	Transplacental	200 Milligram, Once Daily (Qd)		Not Reported
	Sulphasalazine			S	Transplacental	1 Gram, Once Daily (Qd)		Not Reported
	Naproxen			S	Transplacental	500 Mg Sos		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419447	EXPEDITED (15-DAY)		HO	CA-ROCHE-2543639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Skin Ulcer	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419459	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419536	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543693		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Investigation Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419543	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543636			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported

	Tylenol 8 Hr Arthritis Pain	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419562	EXPEDITED (15-DAY)		OT	CA-ROCHE-2547861			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419637	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0861		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Adrenal Disorder; Amnesia; Arthralgia; Asthma; Blood Pressure Increased; Bronchitis; Burning Sensation; Cough; Diarrhoea; Dysgeusia; Dyspnoea; Emotional	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Quetiapine Fumarate			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported

Distress; Emphysema; Fatigue; Furuncle; Genital Herpes Simplex; Head Injury; Headache; Herpes Virus Infection; Hypertension; Inflammation; Insomnia; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Respiratory Failure; Rhinorrhoea; Secretion Discharge; Sleep Disorder; Urine Odour Abnormal; Weight Increased	Actemra	S	Subcutaneous	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Alendronate Sodium	C	Unknown	Not Reported
	Amlodipine	C	Unknown	Not Reported
	Ativan	C	Unknown	Not Reported
	Lipitor	C	Unknown	Not Reported
	Methadone	C	Unknown	Not Reported
	Pantoloc	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Valtrex	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419638	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-844506		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actonel			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419785	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543704			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419860	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1183922		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Leflunomide			S	Oral			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419878	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543667		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419889	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183510		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug	Alendronate Sodium			S	Unknown			Actavis
	Asa			S	Unknown			Not Reported
	Calcium			S	Unknown			Not Reported

Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Fosinopril		S	Unknown	Teva
	Methotrexate		S	Unknown	Barr
	Morphine		S	Unknown	Not Reported
	Actemra		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Simponi		S	Unknown	Not Reported
	Synthroid		S	Unknown	Not Reported
	Tylenol		S	Unknown	Not Reported
	Tylenol		S	Unknown	Not Reported
	Vitamin D		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17419965	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543743			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420198	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Anakinra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420209	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543007		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety;	Actemra			S	Unknown			Not Reported

Asthenia; Contraindicated Product Administered; Depression; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420556	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543700			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420679	EXPEDITED (15-DAY)		OT	CA-BAXTER-2020BAX002873			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Disease Risk Factor; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Therapeutic Product Effect Decreased	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	Dosage Form Not Specified		Baxter
	Cimzia			S	Unknown	Single-Use Prefilled Syringe; Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form Solution Subcutaneous		Not Reported
	Imuran			S	Unknown	Dosage Form Not Specified		Not Reported
	Plaquenil			S	Unknown	Tablets		Not Reported
	Simponi			S	Unknown	Dosage Form Solution		Not Reported

				Subcutaneous	
	Arava	C	Unknown	Tablets	Not Reported
	Azithromycin	C	Unknown	Dosage Form Not Specified	Not Reported
	Celebrex	C	Unknown		Not Reported
	Ezetrol	C	Unknown	Tablets	Not Reported
	Methotrexate	C	Unknown	Dosage Form Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420765	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020062981			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Retinopathy	Methotrexate Sodium			S	Oral	200 Mg, Weekly		Pfizer
	Sulfasalazine			S		1500 Mg, 2x/Day		Pfizer
	Plaquenil S			S		200 Mg, 2x/Day		Not Reported
	Xeljanz Xr			C		11 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420793	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543675		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

Otezla	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sirukumab	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Ustekinumab	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Methotrexate	C	Unknown		Not Reported
Orencia	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420910	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020060246		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral; Retinopathy	Methotrexate Sodium			S	Oral	20 Mg Weekly		Pfizer
	Hydroxychloroquine			S		400 Mg, Daily		Not Reported
	Leflunomide			S		10 Mg, Daily		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Monthly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17421152	EXPEDITED (15-DAY)		OT	NVSC2020US039748		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Hypertrophic Cardiomyopathy; Thrombocytopenia; Ventricular Hypertrophy	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Novartis
	Metoprolol			C	Unknown			Not Reported
	Losartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17421587	EXPEDITED (15-DAY)		OT	CA-ROCHE-2547897		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Rituxan			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Salazopyrina			S	Unknown			Not Reported
	Align			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17421821	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543659			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	365.0		Not Reported
	Arava			S	Unknown			Not Reported

Product Effect Decreased	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel		S	Unknown		Not Reported
	Gold		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown	19.0 Years	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	2.0 Years	Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown	2.0 Years	Not Reported
	Lyrica		C	Oral		Not Reported
	Prednisone		C	Oral		Not Reported
	Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17422215	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-04546		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Etanercept			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported
	Prednisone			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17422354	EXPEDITED (15-DAY)		OT	CA-ROCHE-2549749		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17422367	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009280			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Orencia			S	Unknown			Bristol Myers Squibb
	Etanercept			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17428134	DIRECT	Y	OT				Prefer not to disclose	USA

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

No Adverse Event	Hydroxychloroquine Generic Manufactured By Zydus Pharmaceutical		S	Oral	Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2020	12770694	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076721		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Joint Injury; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	10 Milligram/Kilogram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	2 Milligram, Qd		Not Reported
	Hydromorphone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2020	13188059	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2017GMK026159			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Intentional Product Use Issue; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Pleural Thickening; Presbyacusis; Renal Impairment;	Gabapentin			S	Oral	100 Mg, Bid		Glenmark
	Gabapentin			S	Unknown	100 Mg, Bid		Glenmark
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw (Solution Subcutaneous)		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Fentanyl Citrate			S	Epidural	Unk		Not Reported
	Fentanyl Matrix			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qw		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qw		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Od		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Od, 1 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Od, 1 Every 1 Day		Not Reported
	Arava			S	Oral	20 Mg, Od		Not Reported
	Arava			S	Unknown	Unk		Not Reported

Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Leflunomide	S	Oral	20 Mg, Od 1 Every 1 Day	Not Reported
	Apo Gabapentin	S	Oral	100 Mg, Bid (2 Every 1 Day)	Not Reported
	Apo Gabapentin	S	Unknown	Unk	Not Reported
	Apo Celecoxib	S	Oral	Unk	Not Reported
	Celecoxib	S	Oral	Unk	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Once Every 3 Weeks (Solution Intramuscular)	Not Reported
	Myochrysine	S	Intramuscular	Unk(Solution Intramuscular)	Not Reported
	Myochrysine	S	Intramuscular	Unk(Solution Intramuscular); Once Every 3 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
	Orencia	S	Subcutaneous	Unk, Qw, 1 Every 1 Week	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, 1 Every 3 Weeks	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
	Sulfasalazine	S	Oral	2.5 Mg, Od	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
	Sulfasalazine	S	Oral	2.5 Mg, Od, 1 Every 1 Day	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Mg, Once Every 1 Month	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	468 Mg, Once Every 1 Month	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported

Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Od	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	1 Df, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	400 Iu, Qd	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Esomeprazole /01479302/	C	Unknown	40 Mg, Bid	Not Reported
Esomeprazole /01479302/	C	Unknown	400 Mg, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Nasonex	C	Nasal	2 Df, Bid (Spray, Metered Dose)	Not Reported
Nasonex	C	Unknown	2 Df, Bid	Not Reported
Nasonex	C	Nasal	2 Df, Bid	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Oral	10 Mg, Unk	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Oral	Unk, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Mg, Od	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	5 Mg, Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Od	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Cyclical	Not Reported
Trazodone Hydrochloride	C	Unknown	Unk	Not Reported
Acetaminophen W/Oxycodone	C	Unknown	1 Df, Prn	Not Reported

Hydrochloride				
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Df, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Once Every 4 Weeks (Intravenous Solution)	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Once Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C	Unknown	Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk (1 Every 2 Weeks)	Not Reported
Actonel	C	Unknown	36 Mg, Qw	Not Reported
Actonel	C	Unknown	Unk	Not Reported
Tylenol /00020001/	C	Oral	1000 Mg, Od	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Vitamin D /00107901/	C	Unknown	400 Df, Qd	Not Reported
Vitamin D /00107901/	C	Unknown	Unk	Not Reported
Multivitamin /00097801/	C	Unknown	Unk	Not Reported
Omega 3 /01333901/	C	Unknown	1200 Mg, Bid	Not Reported
Omega 3 /01333901/	C	Unknown	Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Tecta	C	Unknown	40 Mg, Qd	Not Reported
Biotin W/Calcium Pantothenate/Colec/06004901/ Docosahexaenoic Acid	C	Unknown	Unk 1 Df, Qd (1 Every 1 Day)	Not Reported Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported

Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid W/Eicosapentaenoic Acid	C	Unknown	1200 Mg, Bid	Not Reported
Docosahexaenoic Acid W/Eicosapentaenoic Acid	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Fish Oil	C	Unknown	1200 Mg, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nexium /01479302/	C	Unknown	40 Mg, Bid	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Cyclical	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Unk, Unk	Not Reported
Pantoprazole	C	Unknown	400 Mg, Od	Not Reported
Pantoprazole	C	Unknown	40 Mg, Od	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Perfenazine	C	Oral	10 Mg, Unk	Not Reported
Perfenazine	C	Unknown	40 Mg, Od, 1 Every 1 Day	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk, Od, 1 Every 1 Day	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported

Vit D3	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Od	Not Reported
Fergon	C	Unknown	300 Mg, Od	Not Reported
Nortriptyline	C	Urethral	Unk	Not Reported
Vitamin E /00110501/	C	Unknown	Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Tecta	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Omega-3 /01866101/	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Oral	Unk, Qd	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Lomotil /00034001/	C	Unknown	Unk	Not Reported
Actonel	C	Unknown	36 Mg, 1 Every 1 Week	Not Reported
Ferrous Gluconate	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Diphenoxylate	C	Unknown	2.5 Mg, Od	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Genteal /00445101/	C	Unknown	Unk	Not Reported
Genteal /00445101/	C	Unknown	Unk	Not Reported
Oxycodone Hydrochloride W/Oxycodone Terephtha	C	Unknown	1 Df, Unk	Not Reported
Percocet /00867901/	C	Unknown	Unk	Not Reported
Pyridoxine	C	Unknown	Unk	Not Reported
Vitamin B 12	C	Unknown	Unk	Not Reported
Vitamin B12 Aaa	C	Unknown	Unk	Not Reported

Acetaminophen	C	Oral	1000 Mg, Od (1 Every 24 Hours)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2020	15346014	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178067		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Feb-2020	17422660	EXPEDITED (15-DAY)		DE	CA-AUROBINDO-AUR-APL-2020-007472		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Alendronic Acid			S	Unknown	70 Milligram, 1 Every 1 Week		Aurobindo
	Metformin			S	Unknown	500 Milligram, Two Times A Day		Aurobindo
	Flovent			S	Unknown	Unk		Not Reported
	Furosemide			S	Unknown	40 Milligram		Not Reported
	Ipratropium Bromide;Salbutamol			S	Unknown	Unk		Not Reported
	Lipitor			S	Unknown	10 Milligram		Not Reported
	Losec			S	Unknown	20 Milligram		Not Reported
	Nitrazadon			S	Unknown	10 Milligram		Not Reported

Plaquenil	S	Unknown	300 Milligram, Once A Day		Not Reported
Prednisone	S	Unknown	5 Milligram, Once A Day		Not Reported
Salmeterol Xinafoate	S	Unknown	Unk		Not Reported
Tylenol	S	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	12381245	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016061262		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off Label Use; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Mycophenolate Mofetil Hydrochloride			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	1.5 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Cellcept			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Simponi	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Unk, Qwk	Not Reported
Humira	S	Unknown	40 Milligram	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo Mycophenolate	S	Unknown	Unk	Not Reported
Teva Mycophenolate	S	Unknown	Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Lyrica	S	Oral	Unk	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Mycophenolate	S	Unknown	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	S	Intra-arterial	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Milligram	Not Reported
Prednisone	S	Unknown	25 Milligram, Qd Qd, Decrease Dose Weekly	Not Reported
Prednisone	S	Unknown	1 Dosage Form, Qd	Not Reported
Piroxicam	S	Unknown	Unk	Not Reported
Pregabalin	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Morphine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	14634822	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019395		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Off Label Use; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Mg, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Mg, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown	1.5 Gram, Bid		Not Reported
	Leflunomide			C	Oral	10 Mg, Qd		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	15337218	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-079001			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Adalimumab			C	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported

Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Off Label Use; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	500 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram	Not Reported
	Prednisone	C	Unknown	30 Milligram, Qwk	Not Reported
	Prednisone	C	Unknown	35 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Qmo	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	15400433	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083739		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance;	Orencia			S	Unknown			Bristol Myers Squibb
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported

Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	15978440	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013854		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Stress	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk, Q2wk		Not Reported

Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Advil [Ibuprofen]	C	Unknown			Not Reported
Prednisone	C	Oral	6 Milligram, Qwk		Not Reported
Prednisone	C	Oral	10 Milligram, Qd		Not Reported
Tylenol	C	Unknown			Not Reported
Acetaminophen	C	Unknown			Not Reported
Mefenamic Acid	C	Unknown			Not Reported
Dequalinium Chloride	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	16387192	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-050922			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Off Label Use; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Oral	650 Milligram		Not Reported
	Diphenhydramine			C	Oral	50 Milligram		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	100 Milligram		Not Reported

	Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	16440223	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-056344		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma; Off Label Use	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Desoximetasone			C	Unknown	10 Milligram, Qd		Not Reported
	Diclofenac			C	Unknown	100 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	16496259	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-063555			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported

Anakinra	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Ilaris	S	Subcutaneous		Not Reported
Ilaris	S	Unknown		Not Reported
Methotrexate	S	Intra-arterial		Not Reported
Methotrexate	S	Unknown		Not Reported
Plaquenil S	S	Unknown	Unk	Not Reported
Plaquenil S	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	16671604	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ilaris			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported

Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Oxyquinoline Sulfate	S	Unknown			Not Reported
Oxyquinoline Sulfate	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422875	EXPEDITED (15-DAY)		OT	FR-ROCHE-2548690		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Product Use In Unapproved Indication; Urticarial Vasculitis	Omalizumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422886	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009812			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Simponi			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422888	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009885			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422916	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009843		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Erythema; Gastric Haemorrhage; Nephrolithiasis; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Skin Haemorrhage; Skin Warm	Orencia			S	Unknown			Bristol Myers Squibb
	Procytox			S	Intravenous (not otherwise specified)	200 Milligram		Not Reported
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported

Methotrexate	S	Subcutaneous	12.5 Milligram, Qwk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Humira	S	Subcutaneous	40 Milligram		Not Reported
Azathioprine	S	Unknown			Not Reported
Arava	C	Unknown			Not Reported
Gold	C	Unknown			Not Reported
Levofloxacin	C	Unknown			Not Reported
Codeine	C	Unknown			Not Reported
Fentanyl	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422931	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009742		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422932	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009819			Female	CAN

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

Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Orencia		S	Unknown		Bristol Myers Squibb
	Actemra		S	Unknown		Not Reported
	Arava		S	Oral	20 Milligram	Not Reported
	Enbrel		S	Unknown	50 Milligram	Not Reported
	Humira		S	Subcutaneous	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	20 Milligram, Bid	Not Reported
	Methotrexate		S	Subcutaneous	20 Milligram	Not Reported
	Prednisone		S	Oral	5 Milligram	Not Reported
	Sulfasalazine		S	Unknown	1000 Gram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422933	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422934	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		67 YR	Female	CAN

BMS-2020-009905

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17422987	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010408		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cough; Off Label Use; Pain In Extremity; Pneumonia; Product Use Issue	Abatacept			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17423002	EXPEDITED (15-DAY)		HO	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009209			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Oral	1.5 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2020	17423205	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2020-007468		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	500 Milligram		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	360 Milligram, 1 Every 1 Month		Not Reported
	Hydroxychloroquine			S	Unknown	680 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Every Week		Not Reported
	Methotrexate			S	Unknown	12 Milligram, Every Week		Not Reported
	Methotrexate			S	Oral	10 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Every		Not Reported

Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer					Week	
	Methotrexate		S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate		S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate		S	Subcutaneous	70 Milligram, Every Week	Not Reported
	Methotrexate		S	Unknown	12.5 Milligram, Every Week	Not Reported
	Methotrexate		S	Unknown	10 Milligram, Every Week	Not Reported
	Methotrexate		S	Subcutaneous	12 Milligram, Every Week	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported
	Rituximab		S	Unknown	1000 Milligram, Two Times A Day	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Tocilizumab		S	Unknown	680 Milligram	Not Reported
	Tocilizumab		S	Unknown	360 Milligram 1 Every 1 Month	Not Reported
	Tocilizumab		S	Unknown	360 Milligram	Not Reported
	Alendronate		C	Unknown	70 Milligram, Every Week	Not Reported
	Ciclosporin		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	20 Milligram	Not Reported
	Xeljanz		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	11203581	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015010325		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate Sodium			S	Subcutaneous	20 - 25 Mg, Qwk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Qd		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Vomiting	Xeljanz	S	Oral	5 Milligram	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
	Rituxan	S	Unknown	1 Gram, 1/2	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Unknown	50 Milligram, Q4wk	Not Reported
	Simponi	S	Subcutaneous	50 Milligram, Qmo	Not Reported
	Orencia	S	Subcutaneous	150 Milligram, Qwk	Not Reported
	Orencia	S	Subcutaneous	150 Gram	Not Reported
	Orencia	S	Subcutaneous	150 Milligram, Qmo	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	50 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Reactine [Cetirizine	S	Unknown	Unk	Not Reported

Hydrochloride]					
Hydroxychloroquine Sulfate		S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride		S	Unknown	Unk	Not Reported
Prednisone		S	Unknown	Unk	Not Reported
Prednisone		S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
Cetirizine		S	Unknown	10 Milligram	Not Reported
Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone Acetate		S	Topical	Unk	Not Reported
Naprosyn		C	Unknown	500 Milligram, Bid	Not Reported
Naprosyn		C	Unknown	50 Milligram	Not Reported
Celebrex		C	Unknown	200 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	11271826	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015069415		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder;	Enbrel			S	Subcutaneous	Unk		Amgen
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Aspirin			S	Oral	Unk		Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Aspirin			S				Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported

Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Gold	S			Not Reported
	Diclofenac Potassium	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Sodium Aurothiomalate	S	Oral	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Motrin	S	Unknown	Unk	Not Reported
	Motrin	S			Not Reported
	Motrin	S			Not Reported
	Motrin	S			Not Reported
	Naprosyn	S	Unknown	Unk	Not Reported
	Naprosyn	S			Not Reported
	Naprosyn	S			Not Reported
	Naprosyn	S			Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S			Not Reported
	Plaquenil	S			Not Reported
	Plaquenil	S			Not Reported
	Voltaren	S	Unknown	Unk	Not Reported
	Voltaren	S			Not Reported
	Voltaren	S			Not Reported
	Voltaren	S			Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Diclofenac	S	Topical	Unk	Not Reported
	Vitamin C	S	Unknown	Unk	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Unk	Not Reported
	Sulfamethoxazole	S	Unknown		Not Reported
	Clopidogrel	S	Unknown		Not Reported

Trimethoprim	S	Unknown	Unk	Not Reported
Apo Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo Asa	S	Unknown	325 Mg, Unk	Not Reported
Apo-Sulfatrim	S	Unknown		Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Ibuprofen	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid;Clopidogrel	S	Unknown	Unk	Not Reported
Sulfatrim [Sulfadiazine;Trimethoprim]	S	Unknown	Unk	Not Reported
Asa	S	Unknown	Unk	Not Reported
Gold Sodium Thiomalate	S	Unknown		Not Reported
Tramadol	C	Unknown	Unk	Not Reported
Tramadol Hydrochloride	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	11308664	NON-EXPEDITED		OT	CA-AMGEN-CANSP2011017837		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Amgen
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Plaquenil			S	Oral	400 Milligram		Not Reported

Arthritis; Therapeutic Product Effect Decreased	Apo Hydroxyquine	S	Oral	400 Milligram	Not Reported
	Arava	S	Oral	10 Milligram, Qd	Not Reported
	Arava	S	Oral	10 Milligram, Qd	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Milligram, Qmo	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	1000 Milligram, Qmo	Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	4-8mg. Kg, Monthly	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk, Qmo	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qd	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
	Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Intramuscular	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Intramuscular	25 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported

Naprosyn	C	Unknown	Unk Unk, As Required	Not Reported
Ramipril	C	Unknown	Unk	Not Reported
Asa	C	Unknown	81 Milligram	Not Reported
Asa	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk, As Required	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Lozide	C	Unknown	Unk	Not Reported
Lantus	C	Unknown	Unk	Not Reported
Lantus	C	Subcutaneous	Unk	Not Reported
Acetylsalicylic Acid	C	Unknown	Unk	Not Reported
Acetylsalicylic Acid	C	Unknown	81 Milligram	Not Reported
Naproxen	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Vitamin D3	C		Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	11506729	EXPEDITED (15-DAY)		OT	CA-ROCHE-1632320		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Peripheral Swelling; Rheumatoid Arthritis; Skin Reaction; Skin Swelling; Swelling; Therapeutic	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Response Decreased	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12215314	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016171322		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder; Lung Disorder; Product Dispensing Error; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic Product Effect Incomplete	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Celecoxib			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	1000 Milligram, Bid		Not Reported
	Plaquenil			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, On Monday-Wednesday-Friday		Not Reported
	Arava			S	Unknown	10 Mg, 4x/Week		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	1 Milligram, Qd		Not Reported
	Prednisone			S		5 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Vitamin B12	C		1200 Ug, 1 Tablet 1 Time Per Day	Not Reported
	Endocet	C		5 + 325mg 1 Tablet 2x/Day As Needed	Not Reported
	Endocet	C		1 Dose 2 Every 1 Day	Not Reported
	Indomethacin	C		Unk	Not Reported
	Pennsaid	C		Unk	Not Reported
	Oxycocet	C		2 Tablets, 4-5 Times Per Week	Not Reported
	Asa	C		325 Mg, Occasionally	Not Reported
	Naprelan	C		1000 Mg, 1-2 Times Per Month	Not Reported
	Metoprolol	C		75 Milligram, Bid	Not Reported
	Folic Acid	C		5 Mg, 3x/Week	Not Reported
	Bisoprolol	C		5 Milligram, Qd	Not Reported
	Lax-A-Day	C		Occasionally	Not Reported
	Omega 3	C		12000 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12335793	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2016054142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Gold	S	Unknown	Unk		Not Reported
Plaquenil	S	Oral	Unk		Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12377399	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016252940		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Methotrexate Sodium			S	Intra-arterial	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Lyrica			S	Oral	Unk		Pfizer
	Lyrica			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	1.5 Mg, Bid		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Teva Mycophenolate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Solution Subcutaneous		Not Reported

Simponi	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Cellcept	S	Unknown	Unk	Not Reported
Cellcept	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk Solution Intravenous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk Powder For Solution For Intravenous	Not Reported
Humira	S	Subcutaneous	40 Mg, Weekly	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo Mycophenolate	S	Unknown	Unk	Not Reported
Mycophenolate Mofetil Hydrochloride	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Mycophenolate	S	Unknown	Unk	Not Reported
Piroxicam	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	25 Mg, Qd, Decrease Dose Weekly	Not Reported
Prednisone	S		1 Dosage Form, Qd	Not Reported

	Methotrexate			C		Unk			Not Reported
	Morphine			C	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12570090	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016092146		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Enbrel			S	Unknown	Unk		Amgen
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Neoral			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12726405	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016247224		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Enbrel			S	Unknown	Unk		Pfizer

	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Actemra	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	C		Unk	Not Reported
	Calcium	C		Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Leucovorin	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	12964814	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013262		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Apotex
	Apo-Amitriptyline			S	Unknown	Unk		Apotex
	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Amitriptyline			S	Unknown	Unk		Apotex
	Apo-Diclofenac			S	Topical	Unk		Apotex
	Apo-Prednisone			S	Unknown	5 Mg, Unk		Apotex
	Elavil			S	Unknown	Unk		Apotex
	Arthrotec			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported

	Enbrel		S	Subcutaneous	Unk			Not Reported
	Lyrica		S	Unknown	Unk			Not Reported
	Methotrexate		S	Unknown	Unk			Not Reported
	Naprosyn /00256201/		S	Unknown	Unk			Not Reported
	Plaquenil /00072602/		S	Unknown	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	13237730	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1892490		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Ill-Defined Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	13520473	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038273			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Enbrel	S	Unknown		Not Reported
Humira	S	Subcutaneous	40.0 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous drip		Not Reported
Methotrexate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	13594477	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017081646		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Psoriatic Arthropathy; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk (Single Use Prefilled Syringe)		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q6wk		Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram		Not Reported

	Inflectra	C	Intravenous (not otherwise specified)	400 Mg, (Q 0, 2, 6 Weeks, Then Every 8 Weeks)	Not Reported
	Infliximab	C	Unknown	Unk	Not Reported
	Prednisone	C	Oral	Unk	Not Reported
	Leflunomide	C		Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	13638421	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017086096		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Every 10 Days		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Q4wk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	750 Milligram, Q4wk		Not Reported

Orencia	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Adalimumab	S	Unknown	40 Milligram, 1 Every 14 Days	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Tofacitinib	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Milligram, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
Tofacitinib Citrate	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Methotrexate	C	Subcutaneous	Unk	Not Reported
Methotrexate	C	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Methotrexate	C	Oral	Unk	Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Qd	Not Reported
Rabeprazole Sodium	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	13915192	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017127723		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Enbrel			S	Unknown	Unk		Amgen

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Arthrotec	C	Unknown	Unk	Not Reported
	Arthrotec	C	Oral	Unk	Not Reported
	Imuran	C	Unknown	Unk	Not Reported
	Vitamin D	C		Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Azathioprine	C		Unk	Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	14547724	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018022052		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Urinary Tract Infection	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Unknown	776 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil			C	Unknown	400 Milligram, Qwk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	5 Mg, Bid		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	14556178	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018022358			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tofacitinib Citrate			S	Unknown	Unk		Not Reported

Methotrexate	S	Unknown	25 Milligram, Qwk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Orencia	S				Not Reported
Tofacitinib	S	Unknown	Unk		Not Reported
Sulfasalazine	C		Unk		Not Reported
Leflunomide	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	14612490	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018030916			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Pantoprazole			C	Unknown	Unk Unk, Tid		Not Reported
	Loperamide			C	Oral	Unk		Not Reported
	Bifidobacterium Bifidum			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	14618306	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018031234		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	14619670	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018031034		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Align	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Loperamide	C	Oral	2 Mg, Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Bifidobacterium Bifidum	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	15235072	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0429		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported

Orencia	S	Oral			Not Reported
Apo-Hydroxyquine	S	Oral			Not Reported
Apo-Hydroxyquine	S	Oral	200 Mg 2 Tablet		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Folic Acid	C	Oral	6 Days Per Week		Not Reported
Prednisone	C	Oral			Not Reported
Leflunomide	C	Unknown			Not Reported
Xeljanz	C	Oral			Not Reported
Hydroxychloroquine	C	Unknown			Not Reported
Tofacitinib Citrate	C	Unknown			Not Reported
Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	15389696	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082925			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Mg, Bid		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	5 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd (1 Every 24 Hrs)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported
	Meloxicam	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	15707043	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018174024			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported

	Otezla	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous drip	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16058160	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1021169			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Prednisone	C	Unknown	50 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16201961	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019057998		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Fluctuation; Blood Pressure Increased; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Mesalazine			S	Oral	800 Milligram , 3 Every One Day		Not Reported
	Amlodipine Besylate			S	Oral	5 Milligram, Qd		Not Reported
	Amlodipine Besylate			S	Oral	Unk Unk, Qd		Not Reported
	Amlodipine Besylate			S	Unknown	Unk		Not Reported
	Asacol			S	Unknown	800 Milligram, Tid (Tablet (Enteric Coated))		Not Reported
	Diamicron			S	Unknown	Unk		Not Reported
	Gliclazide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

	Xeljanz	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Oral	650 Milligram	Not Reported
	Atacand Plus	C	Oral	Unk, Qd	Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Milligram	Not Reported
	Crestor	C		Unk	Not Reported
	Depo-Medrol	C	Intra-articular	120.0 Milligram	Not Reported
	Depo-Medrol	C	Intramuscular	120.0 Milligram	Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Ebastine	C		Unk	Not Reported
	Ferrous Gluconate	C	Oral	300 Milligram	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Tylenol [Paracetamol]	C		500 Milligram	Not Reported
	Vitamin D3	C		1000 International Unit, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16342037	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-028219		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural	Gabapentin			S	Oral	100 Milligram 1 Every 2 Weeks		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, 1 Every 1 Month		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram Once In A Week		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form Once In A Week		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Every Week		Not Reported

Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Myochrysine	S	Intramuscular	50 Milligram, 1 Every 3 Week	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligramn Once In A Month	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Sulfasalazine	S	Oral	2.5 Milligram, Once A Day	Not Reported
	Sulfasalazine	S	Oral	2.5 Gram, Once A Day	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	488 Milligram, 1 Every Month	Not Reported
	Docosahexanoic Acid;Eicosapentaenoic Acid	C	Unknown	Unk, 1 Every 2 Weeks	Not Reported
	Nasonex	C	Unknown	Unk, Two Times A Day	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Once A Day	Not Reported
	Trazodone	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Tylenol	C	Oral	1000 Gigabecquerel, Once A Day	Not Reported
	Tylenol	C	Oral	1000 Milligram, Once A Day	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Milligram	Not Reported
	Zoledronic Acid	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16451229	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019260752			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling;	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	50 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer

Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Methotrexate Sodium	S	Unknown	25 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S		Unk	Unknown
	Sulfasalazine	S	Unknown	1 Gram, Bid	Pfizer
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Xeljanz	C		11 Milligram, Qd	Not Reported
	Xeljanz	C		5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16797403	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019147539			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16801343	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019148283		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S				Amgen
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Ibuprofen			C		400 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16805094	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019147544			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16807517	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019148110			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthma; Breast	Enbrel			S	Unknown	Unk		Amgen

Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Fatigue; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mammoplasty; Mitral Valve Disease; Off Label Use; Pneumonia; Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Bactrim	S	Oral	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Imuran [Azathioprine Sodium]	S	Unknown	Unk		Not Reported
	Methotrexate	S	Oral	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Azathioprine Sodium	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16839489	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2019155407			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alopecia	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cimzia			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	16843338	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019155462			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Enbrel			S	Unknown	Unk		Amgen
	Azathioprine			S	Unknown	150 Milligram, Qd		Not Reported

Bromocriptine	S	Unknown	Unk		Not Reported
Ciclosporin	S	Unknown	Unk		Not Reported
Colchicine	S	Unknown	Unk		Not Reported
Dilaudid	S	Unknown	Unk		Not Reported
Doxycycline	S	Unknown	Unk		Not Reported
Gold	S	Unknown	Unk		Not Reported
Humira	S	Unknown	40 Milligram		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd		Not Reported
Mercaptopurine	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Methylprednisolone	S	Unknown	Unk		Not Reported
Pamidronate Disodium	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Tenoxicam	S	Unknown	Unk		Not Reported
Ustekinumab	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17047641	EXPEDITED (15-DAY)		DE, HO, OT	NVSC2019GR038794		57 YR	Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradyphrenia; Brain Oedema; Condition Aggravated; Confusional State; Emotional Disorder; Encephalitis Japanese B; Meningitis Bacterial; Product Use In Unapproved Indication; Speech Disorder; Treatment Failure	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown	Unk		Novartis
	Methotrexate			S				Novartis
	Prednisolone			S	Unknown	Unk		Not Reported
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17203052	NON-EXPEDITED			US-AMGEN-USASP2019212356		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17250153	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-000432		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Pregabalin			S	Unknown	Unk		Not Reported
	Pregabalin Capsules			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Aurobindo
	Celecoxib			S	Unknown	Unk		Aurobindo
	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Celecoxib Capsules			S				Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Allopurinol			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Perphenazine And Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported
	Perphenazine And Amitriptyline Hydrochloride			S	Unknown	Unk		Not Reported
	Apo-Amitriptyline			S	Unknown	Unk		Not Reported

Apo-Azathioprine	S	Unknown	Unk	Not Reported
Apo-Diclo	S	Unknown	Unk	Not Reported
Apo-Diclofenac	S	Topical	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arthrotec	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Celebrex	S			Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Celebrex	S			Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Diclofenac Potassium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Every Week	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Parenteral	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Intravenous (not	Unk	Not Reported

			otherwise specified)		
	Misoprostol	S	Unknown	Unk	Not Reported
	Naprosyn	S	Unknown	Unk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Nifedipine	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	750 Milligram, Every Week	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Winpred	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	1 Dosage Form, Two Times A Day	Not Reported
	Tofacitinib	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17260777	EXPEDITED (15-DAY)		DS	CA-ROCHE-2514939		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17364151	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202001000504			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Diarrhoea; Gastroenteritis Cryptosporidial; Hypogammaglobulinaemia; Leukopenia; Neutropenia; Parasitic Gastroenteritis; Weight Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	5 Months Prior To Admission		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423283	NON-EXPEDITED		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-00169		51 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Porphyria Acute	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423321	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542982		61 YR	Female	CAN

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

Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Malignant Melanoma; Rheumatoid Arthritis; Toe Amputation	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Folic Acid	C		Not Reported
	Prednisone	C	Oral	Not Reported
	Restasis	C	Unknown	Not Reported
	Synthroid	C		Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423346	EXPEDITED (15-DAY)		HO	CA-ROCHE-2543760			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Therapy Non-Responder; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Boric Acid			S	Unknown			Not Reported
	Disodium Edetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Phenylephrine Hydrochloride			S	Unknown			Not Reported
	Rho D Immune Globulin			S	Unknown			Not Reported
	Sodium Borate			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported

	Celebrex	C	Not Reported
	Ibuprofen	C	Not Reported
	Lipitor	C	Not Reported
	Methotrexate	C	Not Reported
	Prednisone	C	Not Reported
	Sulfasalazine	C	Not Reported
	Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423522	EXPEDITED (15-DAY)		OT	CA-ROCHE-2549981			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423991	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3270965-00		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Erythema; Gastric Haemorrhage; Nephrolithiasis; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Skin Haemorrhage; Skin Warm	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Procytox			S	Intravenous (not			Not Reported

otherwise specified)

Levofloxacin	C	Not Reported
Gold	C	Not Reported
Fentanyl	C	Not Reported
Codeine	C	Not Reported
Arava	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423994	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183910		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Oral	10 Milligram Daily;		Not Reported
	Aspirin[Acetylsalicylic Acid]			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423995	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184032			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423996	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184178			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatotoxicity; Nausea; Therapeutic Response Decreased; Transaminases Increased	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Methotrexate			S	Unknown	3.5714 Milligram Daily;		Barr
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Levothyroxine Sodium			S	Oral	.075 Microgram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;		Not Reported
	Azathioprine			C	Unknown	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423999	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2020-CA-1183925			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis;	Leflunomide			S	Oral			Barr

Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Methotrexate	S	Intra-arterial	Barr
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Ilaris Single-Use Vial	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Oxyquinoline Sulfate	S	Unknown	Not Reported
	Oxyquinoline Sulfate	S	Urethral	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not	Not Reported

					otherwise specified)				
	Sulfasalazine			S	Unknown				Not Reported
	Sulfasalazine			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424021	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184242			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Cough; Diarrhoea; Eye Pruritus; Headache; Hepatitis; Nausea; Unevaluable Event; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Baricitinib			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424030	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1184268		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424032	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184252		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424034	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1184199		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Necrosis; Skin Ulcer	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Methotrexate			S				Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Codeine			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424035	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184224		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance	Leflunomide			S	Unknown			Barr
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424036	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184223		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis; Diarrhoea; Gastrointestinal Disorder; Malaise	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424037	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184265			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Barr
	Naproxen			C	Unknown	500 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424056	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184287		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Laboratory Test Abnormal	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Folic Acid	C	Not Reported
	Hyzaar	C	Not Reported
	Venlafaxine Hydrochloride	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424130	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0860		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Balance Disorder; Cardiac Disorder; Coronary Artery Bypass; Dermatitis Allergic; Drug Hypersensitivity; Foot Deformity; Hand Deformity; Infection; Irritable Bowel Syndrome; Lung Neoplasm Malignant; Pain In Extremity; Surgery; Therapeutic Product Effect Decreased; Toe Amputation	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Arnica Montana			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424323	EXPEDITED (15-DAY)		OT	CA-ROCHE-2548729		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

	Infliximab	S			Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Pantoloc [Pantoprazole]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424363	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543625			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	5.0 Years		Not Reported
	Humira			S	Subcutaneous	9.0 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	15.0 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424372	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543685		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Ergocalciferol			C				Not Reported
	Imuran [Azathioprine]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424379	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184207		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424381	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184258			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Orencia			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424446	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543666		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Arava	C	Unknown		Not Reported
	Calcium Carbonate	C			Not Reported
	Cymbalta	C			Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Imitrex [Sumatriptan]	C			Not Reported
	Lyrica	C	Unknown		Not Reported
	Premarin	C			Not Reported
	Sumatriptan Succinate	C			Not Reported
	Tenormin	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424450	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184333		81 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Condition Aggravated; Drug Ineffective; Pain; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424451	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183903		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropod Sting; Drug Hypersensitivity; Drug Ineffective; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Codeine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424479	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0886			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Overdose; Retinopathy	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424513	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0882		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neuropathy Peripheral; Retinopathy	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424557	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184300			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Impaired Work Ability; Pain; Rheumatoid Arthritis; Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424586	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184311		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Foot Deformity; Gait Disturbance; Gastric Disorder	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	1 Every 1 Week		Barr
	Naproxen			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424587	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184310		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency	Leflunomide			S	Oral	10 Mg		Barr
	Methotrexate			S	Unknown	5 Mg		Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported

Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Enbrel	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;		Not Reported
	Prednisone	C	Unknown	50 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424589	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184306			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424592	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184274		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Oral	5 Mg		Barr
	Methotrexate			S	Unknown	5 Mg		Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424593	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184285		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder; Inflammation; Insomnia; Nodule; Pain In Extremity; Pollakiuria; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Mg		Barr
	Leflunomide			S	Unknown	20 Mg		Barr
	Methotrexate			S	Subcutaneous	1 Every 1 Week		Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424594	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184312			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug	Leflunomide			S	Unknown	20 Mg		Barr

Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Methotrexate	S	Subcutaneous	20 Mg, 1 Every 1 Week		Barr
	Methotrexate	S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Varenicline Tartrate	S	Oral	1 Dosage Forms Daily;		Not Reported
	Actemra	S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous			Not Reported
	Enbrel	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Acetaminophen	C				Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown			Not Reported
	Naproxen	C	Unknown			Not Reported
	Oxycodone Hydrochloride	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Rosuvastatin Calcium	C	Unknown			Not Reported
	Tofacitinib Citrate	C	Unknown			Not Reported
	Valtrex	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424595	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184271			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinopathy	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported

	Methotrexate	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424596	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184317		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Liver Injury; Loss Of Personal Independence In Daily Activities; Neck Pain; Nodule; Pain; Pain In Extremity; Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424856	EXPEDITED (15-DAY)		HO	CA-ROCHE-2551552			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424985	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0830		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Anakinra			S	Unknown	100mg		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Celecoxib			S	Unknown			Not Reported
	Celecoxib			S				Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17425593	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542835		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Actemra			S	Unknown			Not Reported

Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Rituxan	S	Intravenous drip	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17425921	EXPEDITED (15-DAY)		CA, HO	CA-ROCHE-2543640			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anaemia Of Chronic Disease; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Haemodilution; Headache; Hepatic Cyst; Hepatic Haematoma; Interferon Gamma Release Assay Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Musculoskeletal Stiffness; Neutropenia; Pulmonary Fibrosis; Pulmonary Mass; Pyrexia; Renal Cyst;	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Isoniazid			C	Unknown			Not Reported

Thalassaemia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17425932	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543671		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17426308	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020066855			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

	Imuran [Azathioprine Sodium]	C	Unk	Not Reported
	Methotrexate	C	1 Every 24 Hours	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17426433	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1184330		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Alendronate Sodium			S	Oral			Actavis
	Leflunomide			S	Oral			Barr
	Prednisone			S	Oral			Actavis
	Prednisone			S	Oral			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Oral	20 Milligram Daily;	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram Daily;	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported
Sulfathalidine	S	Oral		Not Reported
Sulfathalidine	S	Oral	2000 Milligram Daily;	Not Reported
Tofacitinib	S	Unknown	10 Milligram Daily;	Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram Daily;	Not Reported
Topicort	S	Cutaneous		Not Reported
Salazopyrin	C	Unknown		Not Reported
Atasol [Paracetamol]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17426935	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011175			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported

Consciousness; Mobility Decreased	Anakinra		S	Unknown		Not Reported
	Arava		S	Oral		Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous drip		Not Reported
	Simponi		S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427012	EXPEDITED (15-DAY)		HO	CA-ROCHE-2542851		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Parenteral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427045	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183889		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported

Fatigue; Helicobacter Infection; Hot Flush; Joint Swelling; Off Label Use; Synovitis	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Calcium Carbonate	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Sumatriptan Succinate	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Tofacitinib	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427052	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1184155		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated;	Leflunomide			S	Unknown	1 Dosage Forms Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Aclasta	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown	20 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Tramacet	S	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Lorazepam	C	Unknown	1 Milligram Daily;	Not Reported
	Lyrica	C	Oral	300 Milligram Daily;	Not Reported
	Metformin	C	Unknown	1000 Milligram Daily;	Not Reported
	Metformin	C	Unknown	5 Milligram Daily;	Not Reported
	Methylprednisolone Acetate	C	Intramuscular		Not Reported
	Methylprednisolone Acetate	C	Subcutaneous		Not Reported
	Methylprednisolone Acetate	C	Intramuscular		Not Reported
	Methylprednisolone Acetate	C	Subcutaneous		Not Reported
	Nortriptyline Hydrochloride	C			Not Reported
	Nortriptyline Hydrochloride	C			Not Reported
	Nortriptyline Hydrochloride	C	Unknown	20 Milligram Daily;	Not Reported
	Premarin	C	Unknown		Not Reported
	Risedronate Sodium	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported

	Vagifem			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427779	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1183906			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Oral			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427788	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1184415		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood	Rosuvastatin			S	Unknown			Teva
	Piperacillin/Tazobactam			S	Unknown			Not Reported
	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
	Mycophenolate Mofetil			S	Unknown	1000 Milligram Daily;		Teva
	Furosemide			S	Unknown			Ivax
	Ceftazidime			S	Unknown			Not Reported

Pressure Diastolic Abnormal; Blood Pressure Increased; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Hepatic Congestion; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Vancomycin Hydrochloride	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Actonel	C			Not Reported
	Apo-Amiodarone Tablets	C			Not Reported
	Apo-Ketorolac	C			Not Reported
	Diphenhydramine	C			Not Reported
	Eprex Sterile Solution	C			Not Reported
	Escitalopram	C			Not Reported
	Humalog	C			Not Reported
	Hydrochlorothiazide	C			Not Reported
	Hydroxychloroquine	C			Not Reported
	Januvia	C			Not Reported
	Metformin	C			Not Reported
	Methylprednisolone Nos	C			Not Reported
	Metoprolol	C			Not Reported
	Pantoloc /01263204/	C			Not Reported
	Pantoprazole	C			Not Reported
	Potassium Chloride	C			Not Reported
	Risedronate	C			Not Reported
	Slow-K Tab	C			Not Reported
	Tylenol	C			Not Reported
	Ventolin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427953	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184412			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Pain	Rosuvastatin			S	Unknown			Actavis
	Piperacillin/Tazobactam			S	Unknown			Not Reported
	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
	Ceftazidime			S	Unknown			Not Reported
	Cellcept			S	Unknown	1000 Milligram Daily;		Not Reported
	Lasix			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Vancomycin			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Actonel			C				Not Reported
	Apo-Amiodarone Tablets			C				Not Reported
	Diphenhydramine			C				Not Reported
	Eprex Sterile Solution			C				Not Reported
	Escitalopram			C				Not Reported
	Hydrochloroquine			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Insulin Lispro			C				Not Reported
	Januvia			C				Not Reported
	Metformin			C				Not Reported
	Methylprednisolone Nos			C				Not Reported
	Metoprolol			C				Not Reported
	Pantoloc			C				Not Reported
	Pantoprazole			C				Not Reported
	Potassium Chloride (Kcl Reatrd)			C				Not Reported
	Risedronate Sodium			C				Not Reported
	Slow-K Tab			C				Not Reported
	Tylenol			C				Not Reported
	Ventolin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17427971	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184685			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Pneumonitis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Pneumococcal Vaccine Polysacch 23v			C	Unknown			Not Reported
	Prevnar 13			C	Unknown			Not Reported
	Varicella Zoster Vaccine Live			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17428024	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1184585		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Off Label Use; Osteoporotic Fracture; Pain; Synovitis	Leflunomide			S	Unknown	2 Dosage Forms Daily;		Barr
	Naproxen			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17428042	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184562		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Rapamune			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Oral	6 Milligram Daily;		Not Reported
	Tacrolimus			S	Oral	4 Milligram Daily;		Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17428069	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184867		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea; Stress	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported

	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Advil [Ibuprofen]	C	Unknown		Not Reported
	Prednisone	C	Oral	6 Milligram Daily;	Not Reported
	Prednisone	C	Oral	10 Milligram Daily;	Not Reported
	Mefenamic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17428628	EXPEDITED (15-DAY)		DE, OT	IN-FRESENIUS KABI-FK202001491		41 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Infection; Brain Abscess; Nocardiosis; Shunt Infection	Methotrexate (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17428727	EXPEDITED (15-DAY)		OT	CA-ASSERTIO THERAPEUTICS, INC.-CA-2020DEP000090			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Back Pain; Drug Ineffective; Enthesopathy; Hla Marker Study Positive; Pancytopenia; Spinal Pain; Spondyloarthropathy; Synovial Disorder	Diclofenac Potassium			S	Unknown	150 Mg, Qd		Assertio Therapeutics
	Methotrexate			S	Unknown	25 Mg, Every Week		Not Reported
	Naproxen			S	Unknown	1000 Mg, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Qd		Not Reported
	Hydroxychloroquine			C		400 Mg, Qd		Not Reported
	Leflunomide			C		Unk		Not Reported
	Piroxicam			C		20 Mg, Bid		Not Reported
	Prednisone			C		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	11800207	NON-EXPEDITED		OT	CA-AMGEN-KDL279454		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Advil	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Mefenamic Acid	C	Unknown	Unk	Not Reported
	Prednisone	C	Oral	10 Milligram, Qd	Not Reported
	Prednisone	C	Oral	6 Milligram, Qd	Not Reported
	Dequalinium Chloride	C		Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	12103915	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016021127		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

			otherwise specified)		
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	10 Milligram	Not Reported
	Arava	C		Unk	Not Reported
	Sodium Aurothiomalate	C		Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	12584285	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016355320		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Enbrel			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Celecoxib			S		Unk		Pfizer
	Azathioprine			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Neoral			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	13413043	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017051637		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Drug Ineffective; Foot Deformity; Hepatotoxicity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	25 Milligram, Bid		Amgen
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	17.5 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Orencia			S	Unknown	1000 Milligram		Not Reported
	Leflunomide			C	Oral	20 Mg, Qd		Not Reported
	Celebrex			C		200 Mg, Bid		Not Reported
	Wellbutrin			C		300 Mg, Qd		Not Reported
	Vitamin D			C		4000 Iu, Qd		Not Reported
	Risedronate			C	Oral	35 Mg, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	14627389	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018099589			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility	Celebrex			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported

Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Leflunomide	S	Unknown	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous drip			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
	Pantoprazole	C	Unknown	Unk Unk, Tid		Not Reported
	Loperamide	C	Oral	Unk		Not Reported
	Bifidobacterium Bifidum	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	14749800	EXPEDITED (15-DAY)		HO	CA-ROCHE-2103364			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	14750039	EXPEDITED (15-DAY)		HO	CA-ROCHE-2103271			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	14823767	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018055160			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported

	Prednisone		C	Unknown	Unk	Not Reported
	Xeljanz		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	14921647	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044755			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Eye Disorder; Hand Deformity; Infection; Lung Disorder; Musculoskeletal Pain; Off Label Use; Peripheral Swelling; Pulmonary Hypertension	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Tylenol			C	Unknown	8 Hour		Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15313643	EXPEDITED (15-DAY)		HO, OT	GB-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-027152		27 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Adverse Event; Cough; Infection; Lower Respiratory Tract Infection; Malaise; Rash; Sinus Operation; Sinusitis; Swelling	Abatacept			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15635020	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105499		63 YR	Female	CAN

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

Breast Cancer; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia	S	Unknown	750 Mg, Unk		Bristol Myers Squibb
	Actemra	S	Unknown	8.0 Mg, Unk		Not Reported
	Apo-Leflunomide	S	Unknown	20.0 Mg, Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unk		Not Reported
	Methotrexate	S	Unknown	20 Mg, Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam	C	Unknown	Unk		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15661545	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018075758			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S				Pfizer
	Tofacitinib Citrate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Qwk (1 Every 1 Week(S))		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15715431	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018510528			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15803741	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2618078-00			Male	CAN

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

Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Celecoxib	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15953498	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-012379		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate	C	Unknown	0.8 Ml, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16075711	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral	7.5 Milligram		Aurobindo
	Actemra			S	Subcutaneous	Unk, Every Week		Not Reported
	Arava			S	Unknown	20 Milligram, Once A Day		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Every Week		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Mobicox			S	Oral	7.5 Milligram, Once A Day		Not Reported
	Sulfasalazine			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16284954	NON-EXPEDITED		OT	CA-AMGEN-CANSP2014093565		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

	Sulfasalazine	S	Oral	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16721389	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-079076			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	567 Milligram, Qmo		Not Reported
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Milligram, Bid		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16819168	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019399007			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16850473	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019412222			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alopecia	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cimzia			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16865776	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-201909000777			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure; Cardiotoxicity; Dyspnoea Exertional; Hypertrophic Cardiomyopathy; Palpitations; Pulmonary Hypertension; Ventricular Hypertrophy	Hydroxychloroquine			S	Unknown	300 Mg, Qd (For More Than 20 Years)		Concordia
	Metoprolol			C		Unk		Not Reported
	Losartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	16938096	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017005654		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity;	Enbrel			S		50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown

Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Methotrexate Sodium	S	Subcutaneous	20 Mg, Weekly	Unknown
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Weekly	Unknown
	Sulfasalazine	S		Unk	Pfizer
	Varenicline Tartrate	S	Oral	Unk Unk, 1x/Day (Qd)	Pfizer
	Varenicline Tartrate	S	Oral	1 Df, 1x/Day	Pfizer
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Rituxan	S		Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Cyclic (Other Weeks)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		400 Mg, Unk	Not Reported
	Leflunomide	S		20 Mg, Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C		Unk	Not Reported
	Valtrex	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Rosuvastatin Calcium	C		Unk	Not Reported
	Esomeprazole Magnesium/Naproxen	C		Unk	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C		Unk	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Oxycodone Hydrochloride	C		Unk	Not Reported
	Naproxen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17333941	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004127			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17407715	EXPEDITED (15-DAY)		HO, OT	NVSC2020DK037178		71 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Bacterial; C-Reactive Protein Increased; Fatigue; Joint Swelling; Off Label Use; Product Use In Unapproved Indication; Weight Decreased	Methotrexate Sodium			S	Unknown	20 Mg, Qw		Novartis
	Hydroxychloroquine			S	Unknown	250 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425380	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010671			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported

Consciousness; Mobility Decreased; Off Label Use	Anakinra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425391	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-202002000759			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage	Hydroxychloroquine			S	Unknown	1 Dosage Form, Qd, Film Coated Tablet		Concordia
	Eliquis			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425627	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010683		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	2 Every One Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Methotrexate	S	Unknown	20 Milligram	Not Reported
Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	200 Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	C	Unknown		Not Reported
Wellbutrin	C	Oral		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425784	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543668		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S				Not Reported
	Fosamax			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425878	EXPEDITED (15-DAY)		OT	CA-SA-2020SA030850			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Intolerance; Eye Disorder; Lung Disorder; Macular Degeneration	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425951	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184854			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; White Blood Cell Count Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Mg		Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Tofacitinib			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425952	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184569			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17425975	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1184657		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hand	Leflunomide			S	Unknown	20 Milligram Daily;		Barr

Deformity; Mobility Decreased; Off Label Use; Pain; Product Use Issue; Swelling	Methotrexate	S	Subcutaneous	20 Mg, 1 Every 1 Week	Barr
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Sulfasalazine	S	Oral	3000 Milligram Daily;	Not Reported
	Acetaminophen/Oxycodone Hydrochloride/Oxycodone Terephthalate	C			Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C			Not Reported
	Ramipril	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17426616	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184539			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Leflunomide			S	Unknown			Barr
	Atorvastatin			S	Oral	40 Milligram Daily;		Teva
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Asa Ec			C	Oral	81 Milligram Daily;		Not Reported
	Folic Acid			C	Oral			Not Reported
	Vitamin D3			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17426809	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551542			Female	CAN

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

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra		S	Subcutaneous	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide		S	Unknown	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17426843	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184864			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17426861	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184581		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17427313	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2020-0889		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Aphasia; Bradykinesia; Confusional State; Disease Progression; Gait Disturbance; Generalised Tonic-Clonic Seizure; Hemiparesis; Hypoaesthesia; Meningitis Noninfective; Mental Status Changes; Muscle Rigidity; Neurological Symptom; Parkinsonism; Postural Tremor; Resting Tremor	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17429397	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3272487-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline Hydrochloride W/Perphenazine			S	Unknown			Not Reported
	Apo-Amitriptyline			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Diclofenac			S	Topical			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac Sodium W/Misoprostol			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Celecoxib			S	Unknown			Not Reported
	Celecoxib			S				Not Reported
	Diclofenac			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Misoprostol	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Nifedipine	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pregabalin	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Winpred	S	Unknown	Not Reported
	Utofacitinib	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17430681	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184673			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17430922	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020064146		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Fluid Retention; Hepatic Cirrhosis	Sulfasalazine			S	Unknown			Pfizer
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Escitalopram Oxalate			C				Not Reported
	Furosemide			C				Not Reported
	Pantoprazole			C				Not Reported
	Perindopril			C				Not Reported
	Prednisone			C				Not Reported
	Spironolactone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431103	EXPEDITED (15-DAY)		LT, OT	CA-PFIZER INC-2020066727		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Blood Iron Decreased; Blood Pressure Increased; Headache; Interstitial Lung Disease; Joint Swelling; Monocyte Count Increased; Muscle Spasms; Osteoporosis; Oxygen Saturation Decreased; Red Blood Cell Count Decreased; Rheumatoid Arthritis; Walking Aid User	Sulfasalazine			S	Unknown			Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported
	Accupril			C				Not Reported
	Acetaminophen			C	Oral	650 Mg, Unk		Not Reported
	Apo-Atorvastatin			C				Not Reported
	Apo-Hydroxyquine			C				Not Reported
	Apo-Prednisone			C				Not Reported

Apo-Zopiclone	C				Not Reported
Diphenhydramine	C	Oral	50 Mg, Unk		Not Reported
Gabapentin	C				Not Reported
Lactaid	C				Not Reported
Lactulose	C				Not Reported
Levemir	C				Not Reported
Methadone	C				Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
Nabilone	C				Not Reported
Novorapid	C				Not Reported
Pantoprazole	C				Not Reported
Pms-Cetirizine	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431408	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184850		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Synovitis; Throat Tightness	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431443	EXPEDITED (15-DAY)		DE	CA-TEVA-2020-CA-1187200		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Prednisone			S	Unknown	5 Milligram Daily;		Actavis

Alendronate Sodium	S	Unknown			Actavis
Ipratropium Bromide And Salbutamol Sulphate Inhalation Solution	S	Unknown			Teva
Metformin	S	Unknown	1000 Milligram Daily;		Actavis
Flovent	S	Unknown			Not Reported
Lasix	S	Unknown			Not Reported
Lipitor	S	Unknown			Not Reported
Losec	S	Unknown			Not Reported
Nitrazadon	S	Unknown			Not Reported
Plaquenil	S	Unknown	300 Milligram Daily;		Not Reported
Salmeterol Xinafoate	S	Unknown			Not Reported
Tylenol	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431642	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011673		30 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	600 Milligram, Qmo		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431933	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-009197			Female	CAN

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

Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia	S	Unknown			Bristol Myers Squibb
	Actemra	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17431942	NON-EXPEDITED			NVSC2020US043346		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Herpes Zoster	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown	40 Mg, Qd		Not Reported
	Prednisone			S	Unknown	20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17432560	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020026034		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Folic Acid	C		Unk	Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17432570	EXPEDITED (15-DAY)		HO, OT	CA-BAXTER-2020BAX002983		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb Fracture	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown	Dosage Form: Not Specified		Baxter
	Arava			S	Oral	Dosage Form:Tablet		Not Reported
	Cimzia			S	Unknown	Dosage Form: Solution Subcutaneous, Singe Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Form: Not Specified		Not Reported

	Plaquenil	S	Oral	Dosage Form: Tablet	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17432595	EXPEDITED (15-DAY)		HO	CA-GLENMARK PHARMACEUTICALS-2020GMK046108			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral	100 Mg, Unk		Glenmark
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, 1 Every 1 Month		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Od		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qw		Not Reported
	Myochrysine			S	Intramuscular	50 Mg, 1 Every 3 Weeks; Formulation: Solution Intramuscular		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	2.5 G, Od		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Aclasta			C	Unknown	Unk; Formulation: Solution Intravenous		Not Reported
	Docosahexaenoic Acid W/Eicosapentae/06850301/			C	Unknown	Unk		Not Reported
	Nasonex			C	Unknown	Unk; Formulation: Spray, Metered Dose		Not Reported

	Prednisone		C	Unknown	Unk	Not Reported
	Trazodone		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17432621	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011197		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Supeudol			C	Unknown	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17432649	EXPEDITED (15-DAY)		HO, LT	CA-BAXTER-2020BAX002993		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Procytox (Cyclophosphamide) 2000mg/Vial			S	Unknown			Baxter
	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)	Dosage Form: Not Specified		Baxter
	Apo-Azathioprine			S	Unknown	Dosage Form: Tablets		Not Reported
	Apo-Azathioprine			S	Unknown	Dosage Form: Tablets		Not Reported
	Apo-Azathioprine			S	Unknown	Dosage Form: Tablets		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Mycophenolate Mofetil	S	Unknown	Dosage Form: Not Specified	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous	Not Reported
	Rituxan	S			Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Diphenhydramine Hydrochloride	C	Unknown		Not Reported
	Methylprednisolone	C	Unknown		Not Reported
	Methylprednisolone Sodium Succinate	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	17450144	DIRECT						Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Hydroxychloroquine			S				Not Reported
	Leucinamide			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	11213498	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015060003		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Arthropathy; Asthma; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Apo Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Activities; Musculoskeletal Stiffness; Pain; Pneumonia; Pruritus; Pulmonary Fibrosis; Rheumatoid Arthritis; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Sulfasalazine	S	Unknown	Unk	Not Reported
	Salicylates Nos	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Imuran [Azathioprine]	S	Unknown	Unk	Not Reported
	Methyl Salicylate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Every 24 Hour	Not Reported
	Prednisone	C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	11290381	EXPEDITED (15-DAY)		OT	CA-ROCHE-1610671		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3 Years, Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 1 Year		Not Reported

Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Rheumatoid Arthritis; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Unknown	Therapy Duration: 9 Years	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 1 Year	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 1 Year	Not Reported
	Arava	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	11.0 Years	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Vaginal		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Ativan	C	Unknown		Not Reported
	Cortisone	C	Intramuscular		Not Reported
	Cortisone	C	Intra-articular		Not Reported
	Cortisone	C	Oral		Not Reported
	Darifenacin	C	Unknown	As Required	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	As Required	Not Reported
	Furosemide	C	Unknown		Not Reported
	Loperamide	C	Unknown		Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown		Not Reported

Omnaris	C	Unknown	Spray, Metered Dose		Not Reported
Pantoprazole Sodium	C				Not Reported
Synthroid	C				Not Reported
Vagifem	C	Unknown	Vaginal Tablet		Not Reported
Anakinra	C				Not Reported
Abatacept	C				Not Reported
Leflunomide	C	Unknown			Not Reported
Lasix [Furosemide]	C	Unknown			Not Reported
Dyclonine Hydrochloride	C				Not Reported
Enablex [Darifenacin]	C	Unknown	Tablet (Extended Release)		Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Tablet (Enteric Coated)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	11713409	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015115197		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Naproxen			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 Gram, Unk		Not Reported
	Sulfasalazine			S	Oral	5000 Milligram, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Qmo		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Milligram, Bid		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported

	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Oral	5 Milligram (2 Every One Weeks)	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Qwk	Not Reported
	Risedronate	C	Oral	35 Milligram, Qwk	Not Reported
	Naroxin	C		Unk	Not Reported
	Arava	C	Oral	20 Milligram, Qd	Not Reported
	Folic Acid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	11999139	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1704038		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	12021392	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016014877		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S				Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	8 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	750 Milligram		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported

Gold	S	Unknown	50 Milligram		Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	20 Milligram		Not Reported
Leflunomide	S	Oral	20 Milligram		Not Reported
Sodium Aurothiomalate	S	Parenteral	50 Milligram		Not Reported
Meloxicam	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	12336694	NON-EXPEDITED		DS, HO, OT	CA-AMGEN-CANSP2015094586		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	20 Milligram, Qd		Amgen
	Etanercept			S	Subcutaneous	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Etanercept			S				Amgen
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported

Ineffective; Drug Intolerance; Enthesopathy; Erythema; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Pain; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Certolizumab Pegol	S	Unknown	Unk	Not Reported
	Ustekinumab	S	Subcutaneous	Unk	Not Reported
	Apremilast	S	Unknown	Unk	Not Reported
	Apremilast	S	Oral	30 Milligram, Bid	Not Reported
	Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
	Ibuprofen	S	Oral	600 Milligram, Every 3-4 Hours Regularly	Not Reported
	Ibuprofen	S	Oral	600 Milligram, Q4h	Not Reported
	Ibuprofen	S	Oral	600 Milligram	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Golimumab	S	Subcutaneous	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Cyclosporin	S	Unknown	Unk	Not Reported
	Cyclosporin	S	Unknown	Unk	Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S			Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S			Not Reported
	Otezla	S	Oral	30 Milligram, Bid	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Otezla	S			Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Motrin	S	Oral	600 Milligram	Not Reported

Motrin	S	Unknown	6 Df, Qd	Not Reported
Motrin	S	Oral	600 Milligram, Qd	Not Reported
Motrin	S	Oral	Unk, Qd	Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
Alendronate Sodium	S	Unknown	70 Milligram 4 Every One Week	Not Reported
Methotrexate	S	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Not Reported
Methotrexate	S	Unknown	2.5 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	12 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	10 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Unknown	70 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	2.5 Milligram, Qmo	Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	7.5 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Oral	10 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 4 Times/Wk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 4 Times/Wk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not	1000 Milligram, Bid	Not Reported

		otherwise specified)		
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Cosentyx	S	Subcutaneous	300 Milligram, Qmo	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Rituximab	S			Not Reported
Celebrex	S	Oral	200 Milligram, Bid	Not Reported
Methotrexate Sodium	C		2.5 Milligram 4 Tablets, Once A Week	Not Reported
Methotrexate Sodium	C	Oral	4.0 Dosage Form, Qwk	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Milligram	Not Reported
Mogadon	C	Unknown	5 Milligram	Not Reported
Febuxostat	C	Unknown	80 Milligram, Bid	Not Reported
Colchicine	C	Oral	0.6 Milligram	Not Reported
Colchicine	C	Oral	6 Milligram	Not Reported
Acide Folique	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C		50 Milligram	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Oxycodone	C		40 Milligram	Not Reported
Oxycodone	C		10 Milligram	Not Reported
Uloric	C	Oral	80 Milligram, Bid	Not Reported

	Uloric	C	Oral	8 Milligram, Bid	Not Reported
	Oxyneo	C	Unknown	40 Milligram	Not Reported
	Oxyneo	C	Unknown	10 Milligram	Not Reported
	Benadryl	C	Unknown	Unk	Not Reported
	Dexilant	C	Unknown	Unk	Not Reported
	Gravol	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Naproxen	C		500 Milligram	Not Reported
	Cannabis Sativa	C		Unk	Not Reported
	Actonel	C	Oral	35 Milligram, Qwk	Not Reported
	Vitamin D 3	C	Oral	2000 International Unit	Not Reported
	Risedronate Sodium	C	Oral	35 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	12598409	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2015389516		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Blood Pressure Fluctuation; Body Temperature Decreased; Bone Density Abnormal; Chills; Cough; Deafness; Decreased Appetite; Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypercholesterolaemia; Infection; Insomnia; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise;	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Lower Doses Initially & Increased Over The Yrs Around 1997		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, 1x/Day		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25,Unk, Qd		Unknown

Mood Swings; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Oropharyngeal Pain; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Rosacea; Somnolence; Stress; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; Weight Increased	Methotrexate Sodium	S	Subcutaneous	25 Mg, Weekly	Unknown
	Sulfasalazine	S	Oral	1 G, 2x/Day: 6 Months	Pfizer
	Methylprednisolone Sodium Succinate	S	Intravenous (not otherwise specified)	100 Milligram	Pfizer
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	S	Oral	25 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	50 Milligram, Unk	Not Reported
	Prednisone	S	Oral	3 Milligram, Qd	Not Reported
	Prednisone	S	Oral	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Acetaminophen	S	Oral	650 Milligram	Not Reported
	Indocid	S		Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, 1x/Day, For One Year	Not Reported
	Leflunomide	S	Unknown	20 Mg, Daily (For 1 Year)	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	S	Oral	50 Milligram	Not Reported
	Ciprodex [Ciprofloxacin Lactate]	C		Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Indomethacin [Indometacin]	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	480 Milligram, Cyclical	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, 1x/Day	Not Reported
	Gold (198 Au) Colloidal	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	50 Milligram, Unk	Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Qd	Not Reported
	Apo-Prednisone	S	Oral	25 Milligram, Qd	Not Reported

Apo-Leflunomide	S	Oral	20 Milligram, Qd		Not Reported
Gold	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Arava	S	Oral	20 Milligram, Qd		Not Reported
Cimzia	S	Subcutaneous	Unk (Single Use Prefilled Syringe)		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 1x/Day		Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Mg, 2x/Day		Not Reported
Indometacin	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported
Xeljanz	C	Oral	Unk, 2x/Day		Not Reported
Folic Acid Aventis	C	Oral	Unk, Weekly		Not Reported
Folic Acid Aventis	C	Oral	5 Mg, Unk		Not Reported
Cymbalta	C	Oral	30 Mg, 1x/Day (Nightly)		Not Reported
B Complex [Vitamin B Complex]	C		Unk		Not Reported
Fish Oil	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	12913352	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-037942			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Breath Sounds Abnormal; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Inflammation; Joint Swelling; Loss Of Personal Independence In	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Q4wk		Bristol Myers Squibb
	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Milligram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Unk	Not Reported
	Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	C	Intracardiac	5 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	10 Milligram, Bid	Not Reported
	Prednisone	C	Unknown	8.5 Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Simponi	C	Subcutaneous	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Acetylsalicylic Acid	C	Unknown	Unk	Not Reported
	Actonel	C	Unknown	Unk	Not Reported

Alprazolam	C	Unknown	Unk	Not Reported
Amlodipine	C	Unknown	Unk	Not Reported
Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Morphine Sulfate	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Paroxetine	C	Unknown	Unk	Not Reported
Risedronate	C	Unknown	Unk	Not Reported
Simvastatin	C	Unknown	Unk	Not Reported
Telmisartan	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown		Not Reported
Iron Sucrose	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	13139174	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2011246063		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Intramuscular	25 Milligram, Qwk		Unknown
	Plaquenil			S	Oral	400 Mg, 1x/Day		Not Reported
	Plaquenil			S	Oral	400 Milligram		Not Reported

Orencia	S	Intravenous (not otherwise specified)	1000 Milligram, Qmo	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	1000 Milligram, Qmo	Not Reported
Arava	S	Oral	10 Milligram, Qd	Not Reported
Arava	S	Oral	10 Milligram, Qd	Not Reported
Actemra	S	Intravenous (not otherwise specified)	4-8mg. Kg, Monthly	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk, Qd	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	1 Dosage Form, Qd	Not Reported
Apo Hydroxyquine	S	Oral	400 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Naproxen Sodium	S		Unk	Not Reported
Apo-Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
Ramipril	C		Unk	Not Reported
Asa Arthritis Strength Aspirin	C		81 Mg, Unk	Not Reported
Metformin	C		Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Calcium	C		Unk	Not Reported

Naproxen	C		Unk		Not Reported
Prednisone	C		Unk, As Required		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Lozide	C		Unk		Not Reported
Naprosyn	C		Unk Unk, As Required		Not Reported
Acetylsalicylic Acid	C		81 Mg, Unk		Not Reported
Acetylsalicylic Acid	C		Unk		Not Reported
Lantus	C	Unknown	Unk		Not Reported
Lantus	C	Subcutaneous	Unk		Not Reported
Ergocalciferol	C	Unknown	Unk		Not Reported
Vitamin D3	C		Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	13775805	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017297593		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

U.S. FOOD & DRUG ADMINISTRATION

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	13921718	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017376122		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Enbrel			S		Dose: 730.0		Pfizer
	Enbrel			S		Dose: 731.0		Pfizer
	Enbrel			S		Dose: 4.0 Year		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Dose: 5.0 Month		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Arthrotec			C	Unknown	Unk		Not Reported

	Arthrotec	C	Oral	Unk		Not Reported
	Gold	S		Unk		Not Reported
	Imuran	C	Unknown	Unk		Not Reported
	Vitamin D	C		Unk		Not Reported
	Ergocalciferol	C	Unknown	Unk		Not Reported
	Ergocalciferol	C	Unknown	Unk		Not Reported
	Azathioprine	C		Unk		Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	14187136	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2017170029		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Off Label Use; Osteoporotic Fracture; Pain; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk, Bid		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	14226198	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015231014		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Arthropathy; Deafness;	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer

Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Enbrel	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S			Pfizer
	Methotrexate Sodium	S			Pfizer
	Methotrexate Sodium	S			Pfizer
	Ibuprofen	S	Unknown	Unk	Pfizer
	Sulfamethoxazole W/Trimethoprim	S	Unknown	Unk	Not Reported
	Aspirin	S	Unknown	Unk	Not Reported
	Aspirin	S			Not Reported
	Aspirin	S			Not Reported
	Aspirin	S			Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Voltaren	S	Unknown	Unk	Not Reported
	Voltaren	S			Not Reported
	Voltaren	S			Not Reported
	Voltaren	S			Not Reported
	Naprosyn	S	Unknown	Unk	Not Reported
	Naprosyn	S			Not Reported
	Naprosyn	S			Not Reported
	Naprosyn	S			Not Reported
	Naprosyn	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S			Not Reported
	Plaquenil	S			Not Reported

Motrin	S	Unknown	Unk	Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Diclofenac Potassium	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Oral	Unk	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Diclofenac	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid W/Clopidogrel	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid W/Clopidogrel	S			Not Reported
Acetylsalicylic Acid W/Clopidogrel	S			Not Reported
Acetylsalicylic Acid W/Clopidogrel	S			Not Reported
Vitamin C [Ascorbic Acid]	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Unknown	Unk	Not Reported
Trimethoprim	S	Unknown	Unk	Not Reported
Apo Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo Asa	S	Unknown	325 Mg, Unk	Not Reported
Tramadol	S	Unknown	Unk	Not Reported
Tramadol Hydrochloride	S		Unk	Not Reported
Apo-Sulfatrim	S	Unknown	Unk	Not Reported
Clopidogrel	S		Unk	Not Reported
Sulfamethoxazole And Trimethoprim	S		Unk	Not Reported
Diclofenac	S		Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported

Diclofenac Sodium	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Naproxen	S	Unknown	Unk		Not Reported
Asa	S	Unknown	Unk		Not Reported
Sulfatrim [Sulfadiazine;Trimethoprim]	S	Unknown	Unk		Not Reported
Gold Sodium Thiomalate	S	Unknown	Unk		Not Reported
Tramadol	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	14559058	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018072306		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Pfizer
	Actemra			S	Unknown	776 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	400 Milligram, Qwk		Not Reported
	Xeljanz			C	Unknown	5 Mg, Bid		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	14631653	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018102054		50 YR	Female	CAN

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

Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Enbrel		S	Unknown	Unk	Pfizer
	Methotrexate Sodium		S	Unknown	Unk	Pfizer
	Xeljanz		S	Oral	5 Mg, 2x/Day	Pfizer
	Actemra		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Leflunomide		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Supeudol		C	Unknown	5.0 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	14632234	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016103661		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	Unk		Pfizer
	Etanercept			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly (Qwk)		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk, (Therapy Duration: 730.0)		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram		Not Reported

	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unk	Not Reported
	Arava	C		Unk	Not Reported
	Sodium Aurothiomalate	C		Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	5 Mg, 2x/Day	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15558530	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018149419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis;	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

Osteoporosis; Pneumonia; Synovitis	Methotrexate	S	Unknown	Unk	Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous drip	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sirukumab	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Morphine	S	Unknown	Unk	Not Reported
	Dilaudid	C		Unk	Not Reported
	Wellbutrin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15616222	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2550220-00			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder; Menorrhagia; Surgery; Uterine Haemorrhage	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15632466	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		78 YR	Female	CAN

BMS-2018-105344

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Winpred			S	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15632602	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-110215			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Tremor	Orencia			S	Unknown	40 Mg, Q2wk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
	Pantoprazole Magnesium	C	Oral	40 Mg, Qd	Not Reported
	Tenofovir Disoproxil Fumarate	C	Oral	300 Mg, Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Zopiclone	C	Unknown	7.5 Mg, Qd	Not Reported
	Folic Acid	C	Oral	2.5 Mg, Qd	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15733751	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594183-00		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15756331	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015044981		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Arthropathy; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Vomiting	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Methotrexate Sodium			S	Subcutaneous	Unk, Weekly		Unknown
	Methotrexate Sodium			S	Oral	25 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Bid		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Celebrex			S		200 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, Qd		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Milligram		Pfizer
	Rituxan			S	Unknown	1 G, 1/2		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Unknown	50 Mg, Q4wk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Orencia			S	Subcutaneous	150 Mg, Qwk		Not Reported
	Orencia			S	Subcutaneous	150 G, Unk		Not Reported
	Orencia			S	Subcutaneous	150 Mg, Qmo		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	500 Milligram, Bid		Not Reported
	Naprosyn			S	Unknown	50 Milligram, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported

Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Subcutaneous	Unk	Not Reported
Folic Acid	S	Unknown	500 Milligram	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	50 Milligram	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Fosamax	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone Acetate	S	Topical	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15880461	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016097219		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer

Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Nausea; Off Label Use; Pain; Treatment Failure; Vomiting	Enbrel	S	Subcutaneous	50 Mg, Qw	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Unk	Unknown
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Unk	Unknown
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Unk	Unknown
	Methotrexate Sodium	S	Subcutaneous	Unk	Unknown
	Methotrexate Sodium	S	Unknown	Unk, 1x/Day	Pfizer
	Sulfasalazine	S	Oral	Unk	Pfizer
	Xeljanz	S	Oral	5 Milligram, Bid	Pfizer
	Xeljanz	S	Unknown	Unk, Qd	Pfizer
	Xeljanz	S	Oral	10 Milligram, Qd	Pfizer
	Xeljanz	S	Unknown	Unk Unk, Qd	Pfizer
	Apo-Hydroxyquine	S	Oral	Unk	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Ciclosporin	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Plaquenil S	S	Oral	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported

Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Orencia	S	Subcutaneous	12.5 Mg, Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	200 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Xeljanz Xr	C		Unk	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported

	Actemra	C	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk	Not Reported
	Actemra	C	Intravenous (not otherwise specified)	8 Milligram, Unk	Not Reported
	Actemra	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15931620	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656087-00		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Diclofenac			C				Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	15934011	EXPEDITED (15-DAY)		CA, DS, OT	CA-ABBVIE-19K-028-2656831-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Mood Swings; Neck Deformity; Neck Mass; Pain; Rheumatoid	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported

Arthritis; Treatment Failure	Apo-Prednisone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Indomethacin	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Cymbalta	C		Not Reported
	Folic Acid	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16008854	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016510		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Inflammation;	Diclofenac			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Intra-arterial			Barr
	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Paracetamol			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sinusitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Actemra	S	Subcutaneous		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S			Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Cimzia Single-Use Prefilled Syringe	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Reactine (Cetirizine)	S	Unknown		Not Reported
	Reactine (Cetirizine)	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Plaquenil	S	Unknown		Not Reported

Plaquenil	S			Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Topicort Mild (Desoximetasone)	S	Oral		Not Reported
Topicort Mild (Desoximetasone)	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo Folic	S	Unknown		Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram Daily;	Not Reported
Sarilumab	S	Unknown		Not Reported
Stelara	S	Unknown		Not Reported
Sulfathalidine	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
Xeljanz	S			Not Reported
Leflunomide	C	Unknown		Not Reported
Atasol	C	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported
Acetaminophen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16199946	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019059140		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Q2wk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unk, Single Use Prefilled		Not Reported

				Syringe	
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Simponi	C	Subcutaneous	50 Milligram, Qmo	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Arava	C		Unk	Not Reported
	Leflunomide	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16209335	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019167731		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Fluctuation; Blood Pressure Increased; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Joint Swelling; Musculoskeletal	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Amlodipine Besilate			S	Oral	5 Mg, 1x/Day		Pfizer
	Amlodipine Besilate			S	Oral	Unk, Daily		Pfizer
	Amlodipine Besilate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Asacol			S	Unknown	800 Mg, 3x/Day		Not Reported

Stiffness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Diamicron	S		Unk	Not Reported
	Gliclazide	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Mesalazine	S	Oral	800 Milligram , 3 Every One Day	Not Reported
	Acetaminophen	C	Oral	650 Mg, Unk	Not Reported
	Atacand Plus	C	Oral	Unk, Qd	Not Reported
	Bisoprolol Fumarate	C	Oral	2.5 Milligram	Not Reported
	Crestor	C		Unk	Not Reported
	Depo-Medrol	C	Intra-articular	120.0 Milligram	Not Reported
	Depo-Medrol	C	Intramuscular	120.0 Milligram	Not Reported
	Diphenhydramine	C	Oral	50 Mg, Unk	Not Reported
	Ebastine	C		Unk	Not Reported
	Ferrous Gluconate	C	Oral	300 Milligram	Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg, Unk	Not Reported
	Tylenol [Paracetamol]	C		500 Milligram	Not Reported
	Vitamin D3	C		1000 International Unit, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16216763	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020587		74 YR	Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Treatment Failure	Ramipril	S	Oral	Unk, Once A Day	Aurobindo
	Actemra	S	Intravenous (not otherwise specified)	600 Milligram,1 Every 4 Week	Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate	S	Unknown	1 Dosage Form, Two Times A Day	Not Reported
	Folic Acid	S	Unknown	7 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once A Day	Not Reported
	Levothyroxine	S	Unknown	1 Dosage Form, Once A Day	Not Reported
	Levothyroxine	S	Unknown	Unk, Once A Day	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Every Week	Not Reported
	Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
	Tylenol	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Acetaminophen	S	Unknown	Unk	Not Reported
	Cosopt	S	Unknown	Unk,1 Every 12 Hours	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Dorzolamide;Timolol	S	Unknown	1 Dosage Form, Two Times A Day	Not Reported
	Dorzolamide;Timolol	S	Unknown	Unk, Two Times A Day	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
	Acetaminophen;Caffeine	C	Unknown	Unk	Not Reported

	Tylenol No.2	C	Unknown	Unk	Not Reported
	Diphenhydramine	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16244983	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017146531		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Drug Ineffective; Hepatotoxicity; Off Label Use	Enbrel			S	Subcutaneous	25 Milligram, Bid		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S		200 Mg, 2x/Day		Not Reported
	Orencia			S		1000 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16444954	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033630			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness;	Meloxicam			S	Unknown	Unk		Aurobindo
	Actemra			S	Subcutaneous	160 Milligram, Every Week		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram, Once A Day		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported

Musculoskeletal Pain;
Musculoskeletal Stiffness;
Myalgia; Pain In Extremity;
Peripheral Swelling;
Pulmonary Toxicity; Rash
Maculo-Papular; Rash
Pruritic; Rheumatoid
Arthritis; Rheumatoid
Nodule; Synovial Cyst;
Tenosynovitis; Upper
Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16570014	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-039032		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown	Unk		Aurobindo
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	200 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Milligram, Once A Day		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16570242	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-038959		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased;	Rosuvastatin			S	Unknown	Unk		Aurobindo

Bronchitis; Drug Ineffective; Fatigue; Hypersensitivity; Immunosuppression; Influenza; Insomnia; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Pain; Pain In Extremity; Rash; Therapeutic Response Decreased; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	Unk, 1 Every Four Week	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	800 Milligram, 1 Every 4 Week	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Every Week	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Humalog	C	Unknown	Unk	Not Reported
	Sertraline Hydrochloride	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16622993	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-041372			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Meloxicam			S	Unknown	Unk		Aurobindo
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16804995	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019396451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Hydroxychloroquine	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16817877	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019399512			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthralgia; Asthma; Breast Disorder; Bronchiectasis; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Fatigue; Gastrooesophageal Reflux Disease; Headache; Hypertension; Hypothyroidism; Mammoplasty; Mitral Valve Disease; Off Label Use; Pneumonia; Respiratory Disorder; Rheumatoid Arthritis; Rheumatoid Nodule	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Bactrim			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Azathioprine Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16824457	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019401916		27 YR	Female	CAN

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

Abortion Spontaneous	Enbrel	S	50 Mg, Weekly	Pfizer
	Enbrel	S		Pfizer
	Methotrexate Sodium	S	Unk	Pfizer
	Arava	S	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unk	Not Reported
	Ibuprofen	C	400 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16851776	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019414089			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Enbrel			S	Unknown	Unk		Pfizer
	Doxycycline Hyclate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methylprednisolone			S	Unknown	Unk		Pfizer
	Pamidronate Disodium			S	Unknown	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S	Unknown	150 Milligram, Qd		Not Reported
	Bromocriptine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Mercaptopurine			S	Unknown	Unk		Not Reported
	Tenoxicam			S	Unknown	Unk		Not Reported
	Ustekinumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16865487	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3765		73 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cardiac Failure Congestive; Diverticulitis; Drug Ineffective; Dyspnoea; Eye Disorder; Lung Disorder; Pulmonary Toxicity; Sensitivity To Weather Change; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg On Monday-Wednesday-Friday		Not Reported
	Arava			S	Unknown	4 Times A Week		Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Vitamin B12			C	Unknown			Not Reported
	Endocet			C	Unknown	1 Tablet 2 Times Per Day As Needed,		Not Reported

	Indomethacin	C	Unknown		Not Reported
	Pennsaid	C	Unknown		Not Reported
	Oxycocet	C	Unknown	2 Tablets 4-5 Times Per Week	Not Reported
	Asa	C	Unknown	Occasionaly	Not Reported
	Naprelan	C	Unknown	1-2 Times	Not Reported
	Metoprolol	C	Unknown		Not Reported
	Bisoprolol	C	Unknown		Not Reported
	Lax-A-Day	C	Unknown		Not Reported
	Omega 3	C	Unknown		Not Reported
	Folic Acid	C	Unknown	3 Times/Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	16992212	EXPEDITED (15-DAY)		OT	PT-ACCORD-159728		63 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Disease Progression; Gastrointestinal Disorder; Interstitial Lung Disease; Pulmonary Embolism	Methotrexate			S	Unknown	Unk		Accord
	Infliximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	1 G (Twice, 2 Week Apart), Cyclic(9 Cycles)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17334288	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000391			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blister; Dermatitis Exfoliative Generalised; Eczema; Rash Erythematous; Rash Maculo-Papular; Skin	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia

Exfoliation; Skin Lesion

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17359711	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1177821			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Density Abnormal; Depression; Neuropathy Peripheral	Bisoprolol			S	Unknown	12.5 Milligram Daily;		Duramed
	Calcium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Ramipril			S	Unknown	12.5 Milligram Daily;		Actavis
	Magnesium (Salt Not Specified)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Buprenorphine			S	Unknown	10 Microgram Daily;		Not Reported
	Cyanocobalamin			S	Unknown			Not Reported
	Fish Oil			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Magnesium Gluconate			S	Unknown			Not Reported
	Multivitamins			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rivaroxaban			S	Unknown	15 Milligram Daily;		Not Reported
	Vitamin B6			S	Unknown			Not Reported
	Vitamin D			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17369604	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020017394			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Feeling Abnormal; Rheumatoid Arthritis; Thirst; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Unknown	20 Milligram, 1 Every 1 Days		Not Reported

Azathioprine		S	Unknown	Unk	Not Reported
Celecoxib		S	Unknown	Unk	Not Reported
Methotrexate		S	Unknown	Unk	Not Reported
Methotrexate		S	Subcutaneous	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
Xeljanz		S	Oral	5 Milligram, 1 Every 12 Hours	Not Reported
Prednisone		S	Unknown	Unk	Not Reported
Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17432990	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011159			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17432992	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000447			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin			S	Unknown	Unk		Ipca
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Ipca
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Mg		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433116	EXPEDITED (15-DAY)		HO	CN-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-236669		41 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Phospholipidosis	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Sun
	Hydroxychloroquine			S				Sun
	Prednisone			C	Unknown	5 Mg		Not Reported
	Prednisone			C	Unknown	10 Milligram, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433123	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0805			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Anakinra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous	Not Specified		Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Gold	S			Not Reported
	Methotrexate	C	Unknown	Not Sepcified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433216	EXPEDITED (15-DAY)		HO	CH-ROCHE-2551375		49 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Mabthera			S	Intravenous drip	2x 500 Mg		Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Zaldiar			S	Oral			Not Reported
	Cimifemin			S	Oral			Not Reported
	Pantozol [Pantoprazole Sodium Sesquihydrate]			S	Oral			Not Reported
	Prednisolon [Prednisolone]			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433353	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552659			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Haemorrhage	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Amlodipine Besilate			C	Unknown			Not Reported

	Gabapentin	C	Unknown	Not Reported
	Prednisone	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433355	EXPEDITED (15-DAY)		OT	CA-ROCHE-2547860		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; Neck Pain; Neck Surgery; Off Label Use; Spinal Column Injury; Surgical Failure; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433750	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011515		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Elbow Deformity; Headache; Liver Function Test Increased; Rheumatoid	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Arthritis	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	2 Gram, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433782	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551846		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Drug Intolerance; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433890	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-000495			Unknown	USA

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

Disease Progression; End Stage Renal Disease; Maculopathy; Toxicity To Various Agents	Hydroxychloroquine	S	Unknown	300 Milligram, Qd		Ipca
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid		Ipca
	Prednisone	C	Unknown	Unk		Not Reported
	Mycophenolate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17433987	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551545		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17434002	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551543			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Zostavax	S	Subcutaneous	Powder For Suspension Subcutaneous	Not Reported
	Desoximetasone	C	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported
	Diclofenac	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17434196	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-007972			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Metformin			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Januvia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17434197	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-007975			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Gout; Hypertension; Palpitations	Metformin			S	Unknown	Unk		Aurobindo
	Colchicine			S	Unknown	Unk		Not Reported
	Januvia			S	Unknown	Unk		Not Reported

	Plaquenil	S	Unknown	Unk		Not Reported
	Sumatriptan Succinate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17434810	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020071268		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Neoplasm; Injection Site Reaction; Psoriasis; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17435005	NON-EXPEDITED			NVSC2020US043433		8 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17435041	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1016772		59 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Meningioma	Anastrozole			S	Oral	1 Milligram, Qd		Not Reported
	Tahor			S	Oral	1 Dosage Form, Qd		Mylan
	Plaquenil /00072603/			S	Oral	400 Milligram		Mylan
	Coumadine			S	Oral	Unk		Mylan
	Kardegic			S	Oral	1 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17435118	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020058496		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apathy; Aphasia; Bradykinesia; Confusional State; Disease Progression; Gait Disturbance; Generalised Tonic-Clonic Seizure; Hemiparesis; Hypoaesthesia; Meningitis Noninfective; Mental Status Changes; Muscle Rigidity; Neurological Symptom; Parkinsonism; Postural Tremor; Resting Tremor	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Prednisone			S		10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17435391	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1018354		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure; Hypertrophic Cardiomyopathy; Overdose	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Metoprolol			C	Unknown	Unk		Mylan
	Losartan			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17435435	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2020M1018837		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Drug Ineffective; Intentional Overdose; Pulmonary Oedema;	Hydroxychloroquine			S	Oral	6 G Missing		Not Reported
	Ibuprofen			S	Oral	Unk		Not Reported

Toxicity To Various Agents	Naproxen		S	Oral		Not Reported
	Epinephrine		S	Unknown		Not Reported
	Potassium		S	Unknown	Unk	Not Reported
	Norepinephrine		S	Unknown	Unk	Not Reported
	Sodium Bicarbonate		S	Unknown	Drips	Mylan
	Calcium		S	Unknown	Unk	Mylan
	Dextrose		S	Unknown	Unk	Mylan
	Vasopressin		S	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17436860	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1018093		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Drug Interaction; Palpitations	Escitalopram			S	Oral	20 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	2 Dosage Form, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17483874	DIRECT		DS, OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Depression; Pain	Plaquenil	Y		S	Oral	Quantity:90 Pills;Other Frequency:2x/Day For One Mon;	3 MTH	Zydus Pharm

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	11418532	NON-EXPEDITED		OT	CA-AMGEN-CANSP2013008516		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported

Function Test Increased; Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Humira	S	Subcutaneous	Unk	Not Reported
	Certolizumab Pegol	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	25 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	1 G, Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Arava	S	Unknown	20 Mg, Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Neoral	S	Unknown	Unk	Not Reported
	Prograf	S	Unknown	Unk	Not Reported
	Prograf	S	Oral	3.0 Mg, Q12h	Not Reported
	Prograf	S	Oral	2.0 Mg, Q12h	Not Reported
	Rapamune	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxyquinoline Sulfate	S	Unknown	Unk	Not Reported
	Tacrolimus	S	Unknown	3 Milligram 1 Every 12 Hours	Not Reported
	Azathioprine	C		25 Mg, Unk	Not Reported
	Imuran	C		25 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	11519456	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2015095516		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy;	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	25 Milligram		Not Reported

Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Wound	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk Unk, Qd	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Parenteral	Unk	Not Reported
	Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	1500 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	Unk, Bid	Not Reported
	Sulfasalazine	S	Subcutaneous	1 Gram, Bid	Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	400 Milligram, Qmo	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Arava	S	Oral	20 Milligram	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil	S	Subcutaneous	Unk	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram	Not Reported
Apo-Folic Acid	S	Unknown	1 Unk, Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Fosamax	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	Unk (Intra Corpus Cavernosum)	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	10 Milligram	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Other	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Oral	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Unknown	Unk	Not Reported

Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	25 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	10 Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Cortisone Acetate	S	Oral	25 Milligram	Not Reported
Cortisone Acetate	S	Unknown	Unk (Tablet)	Not Reported
Cortisone Acetate	S	Topical	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	40 Milligram	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown	50 Milligram	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Cortisone	S	Unknown	Unk	Not Reported
Zyrtec [Cetirizine Hydrochloride]	S	Unknown	10 Milligram (5mg/5ml)	Not Reported
Zyrtec [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported

Folic Acid	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	1.0 Milligram	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	10 Milligram	Not Reported
Tocilizumab	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol	C		Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Lisinopril	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported
Prednisolone	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	12370997	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016061225		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Condition Aggravated; Contraindicated Product	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Prescribed Underdose; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	10 Milligram, Bid	Not Reported
	Prednisone	C		5 Milligram, Qd	Not Reported

Prednisone	C	Unknown	10 Milligram		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	12691303	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016051528		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, 1x/Day		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qd		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	8 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	750 Milligram		Not Reported
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported

	Hydroxychloroquine Sulfate	S	Oral	400 Milligram	Not Reported
	Gold	S	Unknown	50 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Sodium Aurothiomalate	S	Parenteral	50 Milligram	Not Reported
	Meloxicam	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	12788076	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-077476		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Fatigue; General Physical Health Deterioration; Granuloma Skin; Headache; Hepatic Enzyme Increased; Hypercalcaemia;	Abatacept			S	Subcutaneous			Bristol Myers Squibb
	Abatacept			S	Unknown			Bristol Myers Squibb
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	25 Milligram,2 Every One Week		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Ustekinumab			S	Subcutaneous			Not Reported
	Apremilast			S	Unknown	60 Milligram, Bid		Not Reported

Hypersensitivity; Infection; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer	Apremilast	S	Oral	30 Milligram, Bid	Not Reported
	Ibuprofen	S	Oral	600 Milligram, Q4h	Not Reported
	Golimumab	S	Subcutaneous		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Ciclosporin	S	Oral	0.6 Milligram	Not Reported
	Apo-Cyclosporine	S	Oral		Not Reported
	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Otezla	S	Oral	30 Milligram, Bid	Not Reported
	Otezla	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Motrin [Ibuprofen]	S	Oral	600 Milligram, Qd	Not Reported
	Motrin [Ibuprofen]	S	Oral	6 Dosage Form, Qd	Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Codeine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate Sodium	C	Unknown	2.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	C	Oral	4 Dosage Form, Qwk	Not Reported
	Methotrexate Sodium	C	Unknown	10 Milligram, Qwk	Not Reported
	Methotrexate Sodium	C	Oral	Unk, Qwk	Not Reported
	Oxyneo	C	Oral	10 Milligram	Not Reported

Oxyneo	C	Oral	40 Milligram		Not Reported
Mogadon	C	Unknown	5 Milligram		Not Reported
Uloric	C	Unknown	80 Milligram, Bid		Not Reported
Colchicine	C	Oral	0.6 Milligram		Not Reported
Nitrazepam	C	Oral	5 Milligram		Not Reported
Oxycodone	C	Unknown	10 Milligram		Not Reported
Oxycodone	C	Unknown	40 Milligram		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported
Febuxostat	C	Unknown	80 Milligram, Bid		Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown			Not Reported
Dexilant	C	Unknown	Unk		Not Reported
Gravol	C	Unknown	Unk		Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram		Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Milligram		Not Reported
Acide Folique	C	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	12890168	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013157		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Gabapentin			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	1 Df, B.I.Wk.		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Esomeprazole Magnesium Trihydrate			S	Unknown	40 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.I.W		Not Reported
	Nexium /01479302/			S	Unknown	40 Mg, Qd		Not Reported

	Plaquenil /00072602/		S	Unknown	200 Mg, Bid	Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported
	Xeljanz		S	Oral	5 Mg, Bid	Not Reported
	Xeljanz		S	Oral	5 Mg, Qd	Not Reported
	Xeljanz		S	Oral	5 Mg, Unk	Not Reported
	Sulfasalazine		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	13946397	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017455		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Etanercept			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Gold			S	Intramuscular	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	14262244	EXPEDITED (15-DAY)		OT	BR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-108976		38 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Intentional Product Use Issue; Maternal Exposure During Pregnancy	Abatacept			S	Intravenous (not otherwise specified)	500 Mg, Qmo		Bristol Myers Squibb
	Ibuprofen			S	Unknown	Unk		Bristol Myers Squibb
	Reuquinol			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	14496561	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007222			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Off Label Use; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Orencia			S	Unknown	125 Mg, Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported

	Tylenol 8 Hr Arthritis Pain	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	14634808	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	14638057	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-058741		40 YR	Female	CAN

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

Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Unk	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Unk	Not Reported
	Apo-Prednisone	S	Oral	Unk Unk, Qd	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Prednisone	S	Oral	20 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	500 Mg, Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Simponi	S	Subcutaneous	50 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Unknown	5 Milligram, Bid	Not Reported
	Rituxan	S	Unknown	1 G, Bid	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	14639973	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Supeudol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15291706	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015415739		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Stress	Enbrel			S	Subcutaneous	Unk Unk, Weekly		Unknown
	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate Sodium			S		Unk		Unknown
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Subcutaneous	Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported

Humira	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Prednisone	C	Oral	10 Mg, 1x/Day		Not Reported
Prednisone	C	Oral	6 Mg, 1x/Day		Not Reported
Mefenamic Acid	C	Unknown	Unk		Not Reported
Advil	C	Unknown	Unk		Not Reported
Dequalinium Chloride	C		Unk		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15305086	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-074825		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Sinusitis;	Abatacept			S	Subcutaneous	125 Mg, Unk		Bristol Myers Squibb
	Aspirin			S	Unknown	Unk		Bristol Myers Squibb
	Ibuprofen			S	Unknown	Unk		Bristol Myers Squibb

Vulval Abscess	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15400274	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083691			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Hypercalcaemia; Infusion Related Reaction; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Ulcer	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	360 Mg, Qmo		Not Reported
	Actemra			S	Unknown	680 Milligram, Qmo		Not Reported
	Alendronate			S	Unknown	70 Mg, Qwk		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	10 Mg, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram, Bid		Not Reported
	Rituxan			S	Unknown	1000 Gram, Bid		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Myochrysine			S	Parenteral	50 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Ciclosporin			C	Unknown	150 Mg, Qd		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15574827	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018445878			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sirukumab			S	Unknown	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported

	Minocycline Hydrochloride	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Dilaudid	C		Unk		Not Reported
	Wellbutrin	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15639542	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-106082		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Mg, Q2wk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Gold			S	Intramuscular	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Penicillamine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous	25 Milligram, 2 Times/Wk		Not Reported
	Imuran [Azathioprine Sodium]			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Azathioprine	C	Oral	200 Mg, Qd	Not Reported
	Cyclophosphamide	C	Intravenous (not otherwise specified)		Not Reported
	Docusate Sodium	C	Oral	100 Milligram, Qd	Not Reported
	Doxycycline	C	Oral	Unk, 2 Every Day	Not Reported
	Elavil [Allopurinol]	C	Unknown	Unk	Not Reported
	Prednisone	C	Oral	8 Mg, Qd	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Oral	1.5 Gram, Bid	Not Reported
	Tobramycin	C	Unknown	0.3 Percent, Qid	Not Reported
	Wellbutrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15727088	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3743			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Otezla	S	Unknown		Not Reported
Otezla	S	Oral		Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Stelara	S	Subcutaneous		Not Reported
Cosentyx	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15934107	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655644-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Arthrotec	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Imuran	C	Unknown		Not Reported
	Azathioprine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15935702	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657574-00		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Oral			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	15984048	EXPEDITED (15-DAY)		OT	DE-ABBVIE-19K-062-2667153-00			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Humira			S	Subcutaneous	Unknownj		Not Reported

Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Apo-Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Unknown	Not Reported
	Plaquenil	S	Oral		Not Reported
	Neoral	S	Oral	Unknown	Not Reported
	Neoral	S	Subcutaneous	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Ciclosporin	S	Subcutaneous	Unknown	Not Reported
	Ciclosporin	S	Oral	Unknown	Not Reported
	Apo-Hydroxyquine	S	Oral	Unknown	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram	Not Reported
	Methotrexate Sodium	S	Subcutaneous	20 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Milligram	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituximab	S	Oral	Unknown	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Methotrexate	S	Oral	20 Mg. Unknown	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg. Unknown	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Unknown	Not Reported

	Xeljanz		C	Oral	Unkown	Not Reported
	Xeljanz		C	Oral	10 Milligram, Qd	Not Reported
	Xeljanz		C	Unknown	2 Other, Qd	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid,	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	16195868	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2741761-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Wellbutrin			C	Oral			Not Reported
	Xeljanz			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	16473690	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1938			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	16831226	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3515			Male	CAN

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

	Mycophenolate Mofetil	S	Unknown	Not Reported
	Teva Mycophenolate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	16841691	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019164824		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Q2wk		Pfizer
	Enbrel			S	Subcutaneous	50 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Qwk		Not Reported
	Plaquenil Sulfate			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk, Single Use Prefilled Syringe		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			C	Subcutaneous	50 Milligram, Qmo		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Arava			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	16859652	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019419622			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Pneumonia	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Pfizer
	Methotrexate Sodium			S	Intra-arterial	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17386166	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020053154			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Rheumatoid Arthritis; Thirst; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Celecoxib			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Milligram, 1 Every 12 Hours		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, 1 Every 1 Days		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17424245	EXPEDITED (15-DAY)		OT	CA-ROCHE-2548656		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Rituximab			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Medroxyprogesterone Acetate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17438913	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-007930		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia;	Meloxicam			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	160 Milligram, Every Week		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Other	80 Milligram	Not Reported
	Diclofenac	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17438985	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552195			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasopharyngitis; Serum Ferritin Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17439382	EXPEDITED (15-DAY)		OT	CA-ROCHE-2547099			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17439437	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-007978			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Product Use In Unapproved Indication;	Metformin			S	Unknown	Unk		Aurobindo
	Metformin			S				Aurobindo
	Cymbalta			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Warfarin Sodium			S	Unknown	Unk		Not Reported

Thrombosis; Uterine Disorder	Azathioprine		C	Unknown	Unk	Not Reported
	Methotrexate		C	Unknown	Unk	Not Reported
	Xarelto		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17439574	EXPEDITED (15-DAY)		HO	CH-SA-2020SA038476		49 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Arava			S	Oral	10 Mg, Qd		Sanofi
	Plaquenil			S	Oral	200 Mg, Qd		Sanofi
	Paracetamol/Tramadol Hydrochloride			S	Oral	Unk		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	2x 500 Mg Every 5 Month		Not Reported
	Cimifemin			S	Oral	13 Mg, Qd		Not Reported
	Pantozol [Pantoprazole Sodium Sesquihydrate]			S	Oral	As Necessary		Not Reported
	Prednisolon [Prednisolone]			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17439700	EXPEDITED (15-DAY)		LT, OT	GR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-237341		40 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aorta Hypoplasia; Atrioventricular Block Second Degree; Foetal Exposure During Pregnancy; Heart Block Congenital; Intracardiac Mass; Respiratory Distress; Ventricular Septal Defect	Acetylsalicylic Acid			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Prednisolone			S	Unknown			Taro

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17439894	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011665		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Prednisone			C	Unknown	300 Milligram, Qd		Not Reported
	Methotrexate			C	Oral	25 Milligram, Qwk		Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17440706	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020074282		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Unknown
	Sulfasalazine			S	Unknown	Unk		Pfizer

Adalimumab	S	Subcutaneous	40 Mg, Unk		Not Reported
Cimzia	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sarilumab	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Folic Acid	C		Unk		Not Reported
Rabeprazole Sodium	C	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17440731	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020073599			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Cough; Diarrhoea; Eye Pruritus; Headache; Hepatitis; Nausea; Vomiting	Methotrexate Sodium			S	Subcutaneous	15 Mg, Unk		Unknown
	Sulfasalazine			S	Unknown	1 G, 1 Every 12 Hours		Pfizer
	Baricitinib			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1x/Day		Not Reported
	Leflunomide			S	Unknown	Unk Unk, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17440835	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020071257		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Pfizer
	Sulfasalazine			S		1000 Mg, 2x/Day		Pfizer

	Etanercept	S		Unk	Pfizer
	Hydroxychloroquine	S	Oral	300 Mg, Unk	Not Reported
	Tocilizumab	S		Unk	Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17441491	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011828			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Kevzara			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown	650 Milligram, Bid		Not Reported
	Aluminum Acetate			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Neurontin			C	Unknown	600 Milligram, Tid		Not Reported
	Premarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17441763	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3283890-00			Male	CAN

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

Condition Aggravated; Drug Ineffective; Eye Disorder; Hand Deformity; Infection; Lung Disorder; Musculoskeletal Pain; Peripheral Swelling; Pulmonary Hypertension	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Acetaminophen		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17442543	EXPEDITED (15-DAY)		CA, OT	GR-ALLERGAN-2008282US			Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia Foetal; Heart Block Congenital; Pregnancy; Respiratory Distress	Prednisolone Unk			S	Transplacental	Unk		Allergan
	Acetylsalicylic Acid			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	11200640	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015202903		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Pneumonia; Pruritus; Pulmonary Fibrosis;	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Apo Hydroxychloroquin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Rheumatoid Arthritis; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Imuran [Azathioprine]	S	Unknown	Unk	Not Reported
	Methyl Salicylate	S	Unknown	Unk	Not Reported
	Salicylates Nos	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Every 24 Hour	Not Reported
	Prednisone	C		10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	11227333	EXPEDITED (15-DAY)		OT	CA-ROCHE-1524822			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Joint Destruction; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	Prior To 2010		Not Reported
	Myochrysine			S	Unknown	Before 2010		Not Reported

	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	11525254	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2015308388		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Off Label Use; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Incomplete; Wound	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Oral	25 Mg, 1x/Day		Pfizer
	Enbrel			S	Unknown	25 Mg, Unk		Pfizer
	Enbrel			S	Unknown	25 Mg, 1x/Day		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, 1x/Day		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk Unk, Qd		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qd		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Intra-arterial	25 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Parenteral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer

Sulfasalazine	S	Oral	1000 Mg, 2x/Day	Pfizer
Sulfasalazine	S	Unknown	1500 Mg, 2x/Day	Pfizer
Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
Sulfasalazine	S	Oral	1000 Mg, 2x/Day	Pfizer
Sulfasalazine	S	Unknown	1500 Mg, 2x/Day	Pfizer
Sulfasalazine	S	Oral	Unk, Bid	Pfizer
Sulfasalazine	S	Subcutaneous	1 Gram, Bid	Pfizer
Sulfasalazine	S	Unknown	1000 Mg, Unk	Pfizer
Paracetamol	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk (Solution Subcutaneous)	Not Reported
Cimzia	S	Unknown	400 Mg, Monthly	Not Reported
Cimzia	S		Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclic Q2wk	Not Reported
Humira	S		Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone	S	Oral	Unk Ointment	Not Reported
Cortisone	S	Unknown	Unk Tablet	Not Reported
Cortisone	S	Oral	25 Mg, Unk Tablet	Not Reported
Cortisone	S		25 Mg, Unk Ointment	Not Reported
Cortisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Mg, 1x/Day (1 Every 24 Hours)	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Fosamax	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	Unk (Intra Corpus Cavernosum)	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Hydrocortisone Acetate	S	Oral	Unk	Not Reported
Hydrocortisone Acetate	S	Other	Unk	Not Reported
Hydrocortisone Acetate	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Cetirizine	S	Oral	10 Mg, Unk	Not Reported

Cetirizine	S	Unknown	10 Mg, Unk	Not Reported
Cetirizine	S	Unknown	10 Milligram (5mg/5ml) Unk Syrup	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	50 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Mg, Unk	Not Reported
Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
Folic Acid	S	Oral	25 Mg, Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	40 Mg, Unk	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	S		1 Mg, Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Golimumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Golimumab	S	Subcutaneous	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Sulfathalidine	S		Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported

	Cosentyx	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Atasol	C	Unknown	Unk	Not Reported
	Ibuprofen	C	Unknown	Unk	Not Reported
	Leflunomide	C	Oral	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	20 Mg, Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Lisinopril	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Prednisolone	C	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	12701616	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1489		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Leucovorin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	14781801	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107063			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Pain; Rash; Squamous Cell Carcinoma; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	14826053	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-036485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Drug Ineffective; Drug Intolerance; Impaired Work Ability; Off Label	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Simponi			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported

Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Remicade	S	Unknown	200 Milligram, Cyclical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15345828	EXPEDITED (15-DAY)		OT	CA-ROCHE-2177475		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Contraindicated Product Administered; Fall; Off Label Use; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	00072603		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15620004	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556866-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Contraindicated Product Administered; Drug	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not			Not Reported

Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure			otherwise specified)			
	Apo-Leflunomide	S	Unknown			Not Reported
	Enbrel	S	Unknown			Not Reported
	Gold	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate	S	Parenteral			Not Reported
	Methotrexate	S	Unknown	Solution		Not Reported
	Leflunomide	S	Oral			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Meloxicam	C	Unknown			Not Reported
	Sulfasalazine	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15634991	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105511			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Tooth Loss	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Rituxan	S	Unknown			Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
Zostavax	S	Intravenous (not otherwise specified)			Not Reported
Zostavax	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Desoximetasone	C	Oral			Not Reported
Desoximetasone	C	Subcutaneous	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Xeljanz	C	Oral	10 Mg, Bid		Not Reported
Diclofenac	C	Subcutaneous	100 Mg, Unk		Not Reported
Cortisone Acetate	C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15811039	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2617171-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported

	Cyclosporine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Gabapentin	C	Oral	Not Reported
	Gabapentin	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Tylenol Arthritis Pain	C	Unknown	Not Reported
	Tylenol Arthritis	C		Not Reported
	Tylenol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15855371	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2015371800		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Week		Pfizer
	Sulfasalazine			S	Unknown	2 G, Unk		Pfizer
	Sulfasalazine			S	Oral	5000 Mg, 1x/Day		Pfizer
	Orencia			S	Unknown	Unk, Monthly		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Apo-Naproxen			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 2x/Day		Not Reported

Rituxan	S		Unk	Not Reported
Naproxen Sodium	S		Unk	Not Reported
Hydroxychloroquine	S		400 Mg, Unk	Not Reported
Prednisone	S		Unk	Not Reported
Apo-Prednisone	S		Unk	Not Reported
Methotrexate Sodium	C	Subcutaneous	25 Mg, Weekly	Not Reported
Naroxin	C		Unk	Not Reported
Risedronate	C	Oral	35 Mg, Weekly	Not Reported
Arava	C	Oral	20 Mg, 1x/Day	Not Reported
Folic Acid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15887790	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1610		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Nausea; Pain; Product Use Issue; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name			S	Subcutaneous			Not Reported

Unknown)			
Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Oral	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Ciclosporin	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Plaquenil S	S	Oral	Not Reported
Plaquenil	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported

Leflunomide	S	Unknown	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Xeljanz Xr	C	Unknown	Not Reported
Simponi	C	Subcutaneous	Not Reported
Actemra	C	Intravenous (not otherwise specified)	Not Reported
Actemra	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15933878	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656787-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pulmonary Toxicity; Therapeutic Product Effect	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Incomplete	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil		S	Unknown	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Celebrex		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	15936329	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657755-00		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Infection; Insomnia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Bp		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16178013	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1035747		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide	Diclofenac Sodium			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis

Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Methotrexate	S	Oral		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate Sodium	S	Oral		Barr
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily; Therapy Duration- 365	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Topicort(Desoximetasone)	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16192832	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2741798-00		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Loss Of Weight; Alopecia; Arthritis; Drug Ineffective; Hepatic Enzyme Abnormal; Myocardial Infarction; Rash	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Clopidogrel Bisulfate			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Acetylsalicylic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16445871	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-056456			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qd		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Rituxan			S	Unknown	1 Gram		Not Reported
	Rituximab			S	Unknown	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16489797	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-2052		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Arthroplasty; Nausea; Oedema; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Rituxan	S	Unknown	1/2	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Cetirizine	S	Unknown		Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Naprosyn	C	Unknown	Not Reported
	Naprosyn	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16801774	EXPEDITED (15-DAY)		OT	PHHY2019CA210752			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16830502	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2929972-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Hip Arthroplasty;	Humira			S	Subcutaneous	Cyclical		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Hypoaesthesia; Joint Swelling; Malaise; Multiple Sclerosis; Musculoskeletal Disorder; Nausea; Vomiting	Plaquenil	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Lyrica	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16839479	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019154934			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; Unevaluable Event; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Tofacitinib			S	Unknown	5 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	16877948	EXPEDITED (15-DAY)		OT	GB-BAUSCH-BL-2019-055587		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin			S	Unknown			Santarus
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17272589	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020013698		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide	Ibuprofen			S	Oral	Unk (200mg Tablets)		Pfizer
	Hydroxychloroquine			S	Oral	Unk (6 G Missing)		Not Reported
	Naproxen			S	Oral	Unk (750mg Tablets)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17278764	EXPEDITED (15-DAY)		OT	NVSC2019CA086426		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Infusion Related Reaction; Joint Swelling; Live Birth; Musculoskeletal Stiffness;	Diclofenac			S	Unknown	50 Mg		Novartis
	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Diclofenac Diethylamine			S	Unknown	Unk		Novartis
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg		Not Reported
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Unknown	0.5 Unk		Not Reported
	Folic Acid			S	Oral	25 Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Etanercept			S	Subcutaneous	50 Mg		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Mg		Not Reported

Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Cimzia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Apo Prednison	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Salazopyrine	S	Oral	1 G, Bid	Not Reported
	Sulfasalazine	S	Oral	500 Mg	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Qd	Not Reported
	Paracetamol	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported

Tocilizumab	S	Subcutaneous			Not Reported
Winpred	S	Oral			Not Reported
Stelera	S	Unknown			Not Reported
Topicort	S	Subcutaneous			Not Reported
Topicort	S	Oral	Unk		Not Reported
Sarilumab	S	Unknown			Not Reported
Apo-Hydroxyquine	S	Unknown			Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk		Not Reported
Tofacitinib Citrate	C	Unknown			Not Reported
Salazopyrin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17442941	EXPEDITED (15-DAY)		OT	CA-ROCHE-2547878		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Venlafaxine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	M-Eslon			C	Unknown			Not Reported
	Morphine			C				Not Reported
	Morphine Sulfate			C				Not Reported
	Statex [Morphine Sulfate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17442962	EXPEDITED (15-DAY)		HO, OT	GR-IPCA LABORATORIES LIMITED-IPC-2020-GR-000567			Unknown	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Heart Disease Congenital; Respiratory Distress	Hydroxychloroquine			S	Transplacental	Unk		Ipca
	Prednisolone			S	Transplacental	Unk		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443256	EXPEDITED (15-DAY)		OT	CA-ROCHE-2549601		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Thyroid Neoplasm	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443328	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553485		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443340	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-237571		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatic Fibrosis; Insomnia; Pain; Rash; Therapeutic Product Effect Incomplete	Venlafaxine			S	Oral	1 Dosage Form, Daily		Sun
	Enbrel			S	Subcutaneous	1 Dosage Form, Weekly		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	300 Milligram, Daily		Not Reported
	Reactine			C	Unknown	10 Milligram, Daily		Not Reported
	Zopiclone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443383	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553490		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Minocycline			C	Unknown			Not Reported
	Penicillamine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443400	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552179		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443467	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553491		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Methotrexate		S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443476	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3283788-00		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Cervical Vertebral Fracture; Drug Ineffective; Drug Interaction; Drug Intolerance; Grip Strength Decreased; Hypophagia; Influenza; Joint Range Of Motion Decreased; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Rheumatoid Arthritis; Upper Limb Fracture; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443486	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552643		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Other			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443552	EXPEDITED (15-DAY)		HO	CA-ROCHE-2552666			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443585	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552671		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Zostavax	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17443944	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011979			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17444031	EXPEDITED (15-DAY)		OT	CA-ROCHE-2554290		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Osteoarthritis; Synovitis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17444871	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187147		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Joint Swelling; Off Label Use; Pain; Pemphigus; Rash; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Cutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrocortisone Acetate			S	Cutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral	25 Milligram Daily;		Not Reported
	Orencia			S	Subcutaneous			Not Reported

Orencia	S	Intravenous (not otherwise specified)			Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Oral	2 Gram Daily;		Not Reported
Sulfasalazine	S	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported
Leflunomide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17444898	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187135			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Weight Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Humira			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17445348	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552836		51 YR	Female	CAN

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

Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Rheumatoid Arthritis; Sleep Disorder	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17445349	EXPEDITED (15-DAY)		OT	NVSC2020CA025358			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Fatigue; Grip Strength Decreased; Hepatitis; Pain	Methotrexate			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	20 Mg		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indomethacin			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Imuran			C	Unknown			Not Reported
	Cortisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17445421	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020073533			Female	CAN

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

Drug Ineffective; Pneumonia	Methotrexate Sodium		S	Unknown	20 Mg, Unk	Pfizer
	Sulfasalazine		S	Unknown	1 G, Every 12hours	Pfizer
	Hydroxychloroquine Sulfate		S	Unknown	400 Mg, Unk	Not Reported
	Leflunomide		S	Unknown	20 Mg, Every Day	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17445771	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020077926			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Disorder; Hepatotoxicity; Pain	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S		500 Mg, Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446119	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-007		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; Cardiomegaly; Incorrect Dose Administered; Maculopathy; Nephropathy Toxic; Renal Failure; Retinal Toxicity	Hydroxychloroquine			S	Unknown			Hikma
	Hydroxychloroquine			S	Unknown			Hikma
	Prednisone			C	Unknown			Not Reported
	Mycophenolate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446901	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1187166			Female	CAN

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

Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased	Prednisone	S	Oral	5 Milligram Daily;		Actavis
	Methotrexate	S	Subcutaneous			Barr
	Actemra	S	Unknown			Not Reported
	Arava	S	Oral			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;		Not Reported
	Orencia	S	Unknown			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Unknown	2000 Gram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446916	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187154			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Drug Intolerance; Foot Deformity; Inguinal Hernia; Interstitial Lung Disease; Joint Dislocation; Periarticular Disorder; Post-Traumatic Neck Syndrome; Rheumatoid Arthritis	Prednisone			S	Unknown	15 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Calcium Carbonate			S	Oral	3 Dosage Forms Daily;		Not Reported
	Celebrex			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Relafen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	3000 Milligram Daily;		Not Reported
	Magnesium Aspartate			C	Oral	3 Dosage Forms Daily;		Not Reported
	Omega 3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446944	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187274			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Diclofenac Sodium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446966	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187287		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Exposure Before Pregnancy; Maternal	Prednisone			S	Unknown			Actavis

Exposure During Pregnancy; Placental Insufficiency; Premature Delivery	Methotrexate		S	Unknown	Barr
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Immune Globulin (Human)		S	Unknown	Not Reported
	Immune Globulin (Human)		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17446970	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187192			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Endodontic Procedure; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Pain; Product Dose Omission; Rash; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tooth Infection; Weight Decreased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Naproxen			C				Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17447221	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187169			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypospadias; Low Birth Weight Baby; Maternal Exposure During Pregnancy; Premature	Prednisone			S	Transplacental			Actavis
	Methotrexate			S	Transplacental			Barr
	Hydroxychloroquine			S	Transplacental			Not Reported

Baby	Immune Globulin (Human)	S	Transplacental		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17447516	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187714			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Sepsis; Therapeutic Response Decreased; White Blood Cell Count Decreased	Prednisone			S	Oral			Actavis
	Methotrexate			S	Unknown			Barr
	Plaquenil			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acyclovir [Aciclovir]			C	Unknown			Not Reported
	Aerius [Ebastine]			C	Oral			Not Reported
	Amitriptyline			C	Oral	25 Milligram Daily;		Not Reported
	Constella			C	Oral	145 Milligram Daily;		Not Reported
	Levofloxacin			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			C	Oral			Not Reported
	Sertraline Hydrochloride			C	Unknown			Not Reported
	Vitamin C [Ascorbic Acid]			C	Oral			Not Reported
	Zomig			C	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17447605	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020073610			Male	CAN

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

Drug Hypersensitivity; Gastric Disorder; Gastric Haemorrhage; Pain; Therapeutic Product Effect Decreased	Methotrexate Sodium	S	Unknown	Unk		Pfizer
	Sulfasalazine	S	Unknown	Unk		Pfizer
	Humira	S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
	Tylenol 8 Hr Arthritis Pain	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2020	17447732	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187228			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Drug Ineffective; Juvenile Idiopathic Arthritis; Red Blood Cell Sedimentation Rate Abnormal	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	14667263	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007994		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Nodule; Osteoporosis; Pain; Rheumatoid Arthritis; Stress	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	200 Mg, Bid		Not Reported

Plaquenil /00072602/	C	Unknown	Unk		Not Reported
Vitamin D /00107901/	C	Unknown	4000 Iu, Qd		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Ergocalciferol	C	Unknown	4000 Iu, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17333171	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527581			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular	Solution Intramuscular		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17448001	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553779		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17448019	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555252			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17448020	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553790		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Noncompliance	Sulfasalazine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17448022	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553470		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Pulmonary Fibrosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2020	17448030	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553811			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Naprosyn [Naproxen]	S	Unknown	Not Reported
	Naprosyn [Naproxen]	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Vioxx	S	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2020	15630530	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105495		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Lyrica			C	Oral	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	1 Df, Qwk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			C	Unknown			Not Reported

	Prednisone	C	Oral	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Feb-2020	17448256	EXPEDITED (15-DAY)		OT	PHHY2019CA055941		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk (Single-Use Prefilled Syringe)		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12310874	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014345227		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased;	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Methotrexate			S		25 Mg, Unk		Pfizer

Loss Of Personal Independence In Daily Activities; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Sulfasalazine	S	Unknown	1 G, Unk	Pfizer
	Rapamune	S		Unk	Pfizer
	Plaquenil	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Certolizumab Pegol	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Neoral	S		Unk	Not Reported
	Prograf	S	Unknown	Unk	Not Reported
	Prograf	S	Oral	3.0 Mg, Q12h	Not Reported
	Prograf	S	Oral	2.0 Mg, Q12h	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxyquinoline Sulfate	S	Unknown	Unk	Not Reported
	Tacrolimus	S	Unknown	3 Milligram 1 Every 12 Hours	Not Reported
	Tacrolimus	S	Oral	3 Milligram, 2 Every 1 Day	Not Reported
	Tacrolimus	S	Oral	2 Milligram, 2 Every 1 Day	Not Reported
	Azathioprine	C		25 Mg, Unk	Not Reported
	Imuran	C		25 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12355072	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2015306460		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase	Etanercept			S	Subcutaneous	Unk		Pfizer
	Etanercept			S		Unk		Pfizer
	Etanercept			S		Unk		Pfizer

Increased; Arthralgia;	Enbrel	S	Subcutaneous	Unk	Pfizer
Arthritis; Arthropathy; Aspartate	Enbrel	S		25 Milligram, 2 Times/Wk	Pfizer
Aminotransferase	Enbrel	S		25 Milligram	Pfizer
Increased; Basal Cell	Enbrel	S		Unk	Pfizer
Carcinoma; Blood	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Pfizer
Creatinine Increased; Blood Parathyroid	Enbrel	S	Unknown	20 Milligram, Qd	Pfizer
Hormone Decreased; Blood Pressure Systolic	Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
Increased; C-Reactive	Sulfasalazine	S	Unknown	Unk	Pfizer
Protein Abnormal;	Sulfasalazine	S	Oral	1 Gram, Bid	Pfizer
Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug	Infliximab Hospira	S	Intravenous (not otherwise specified)	400 Milligram	Not Reported
Eruption; Drug Hypersensitivity; Drug	Infliximab Hospira	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Intolerance; Enthesopathy; Erythema; Erythema; Fatigue; Fear Of Injection;	Ibuprofen	S	Oral	600 Mg, Every 3-4 Hours Regularly	Pfizer
General Physical Health Deterioration; Granuloma	Ibuprofen	S	Oral	600 Mg, Q4h	Pfizer
Skin; Headache;	Ibuprofen	S	Oral	600 Milligram	Pfizer
Hypercalcaemia; Inflammation; Infusion Related Reaction;	Methotrexate Sodium	S	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Pfizer
Insomnia; Joint Injury;	Methotrexate Sodium	S	Unknown	2.5 Milligram, Qwk	Pfizer
Joint Swelling; Loss Of Personal Independence In Daily Activities;	Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Pfizer
Musculoskeletal Stiffness; Nausea; Off Label Use;	Methotrexate Sodium	S	Unknown	15 Milligram, Qwk	Pfizer
Pain; Panniculitis; Peripheral Swelling;	Methotrexate Sodium	S	Unknown	17.5 Milligram, 4 Times/Wk	Pfizer
Product Use Issue;	Methotrexate Sodium	S	Unknown	12 Milligram, 4 Times/Wk	Pfizer
Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid	Methotrexate Sodium	S	Unknown	10 Milligram, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Milligram, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S	Unknown	70 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Unknown	2.5 Milligram, Qmo	Pfizer
	Methotrexate Sodium	S	Oral	10 Milligram, Qwk	Pfizer

Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Methotrexate Sodium	S	Oral	7.5 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Oral	10 Milligram, 4 Times/Wk	Pfizer
	Celebrex	S	Oral	200 Milligram, Bid	Pfizer
	Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qwk	Unknown
	Methotrexate Sodium	S	Subcutaneous	15 Milligram, 4 Times/Wk	Unknown
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, 4 Times/Wk	Unknown
	Methotrexate Sodium	S	Subcutaneous	17.5 Milligram, 4 Times/Wk	Unknown
	Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Cosentyx	S	Subcutaneous	300 Milligram, Qmo	Not Reported
	Apo Ibuprofen	S	Oral	600 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Cyclosporine	S	Oral	Unk	Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Golimumab	S	Subcutaneous	Unk (Solution)	Not Reported
	Ustekinumab	S	Subcutaneous	Unk	Not Reported
	Ustekinumab	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Certolizumab Pegol	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported

Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Unknown	Unk	Not Reported
Apremilast	S	Oral	30 Mg, 2x/Day	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
Cyclosporin	S	Oral	Unk	Not Reported
Cyclosporin	S	Unknown	Unk	Not Reported
Otezla	S	Oral	30 Mg, Bid	Not Reported
Otezla	S			Not Reported
Otezla	S			Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Oral	600 Mg, Unk	Not Reported
Motrin	S	Oral	600 Mg, Every 3-4 Hours Regularly	Not Reported
Motrin	S	Oral	600 Mg, Q4h	Not Reported
Motrin	S	Oral	600.0 Mg, Unk	Not Reported
Motrin	S		6 Df, 1x/Day	Not Reported
Motrin	S	Oral	600 Milligram, Qd	Not Reported
Motrin	S	Oral	Unk, Qd	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Milligram 4 Every One Week	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported

Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Oxyneo	C	Unknown	10 Mg, Unk	Not Reported
Oxyneo	C	Unknown	40 Mg, Unk	Not Reported
Mogadon	C	Unknown	5 Mg, Unk	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day (Freq: 2 Day; Interval: 1)	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C		80 Mg, Bid	Not Reported
Uloric	C	Unknown	Unk Mg, Unk	Not Reported
Uloric	C	Oral	8 Milligram, Bid	Not Reported
Colchicine	C	Oral	0.6 Milligram	Not Reported
Colchicine	C	Oral	6 Milligram	Not Reported
Acide Folique	C		Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nitrazepam	C	Unknown	5 Mg, Unk	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C		50 Milligram	Not Reported
Oxycodone	C	Unknown	40 Mg, Unk	Not Reported
Oxycodone	C	Unknown	10 Mg, Unk	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported

	Febuxostat	C	Unknown	80 Mg, Bid	Not Reported
	Methotrexate Sodium	C	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Not Reported
	Methotrexate Sodium	C		2.5 Milligram 4 Tablets, Once A Week	Not Reported
	Oxycodone Hydrochloride	C	Unknown	10 Mg, Unk	Not Reported
	Oxycodone Hydrochloride	C	Unknown	40 Mg, Unk	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported
	Naproxen	C		500 Milligram	Not Reported
	Cannabis Sativa	C		Unk	Not Reported
	Actonel	C	Oral	35 Milligram, Qwk	Not Reported
	Vitamin D 3	C	Oral	2000 International Unit	Not Reported
	Risedronate Sodium	C	Oral	35 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12690990	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1432		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intramuscular			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	4-8 Mg/Kg		Not Reported

Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S	Oral	Not Reported
Apo-Hydroxyquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Acetylsalicylic Acid	C	Unknown	Not Reported
Calcium	C	Unknown	Not Reported
Lantus	C	Subcutaneous	Not Reported
Lozide	C	Unknown	Not Reported
Metformin	C	Unknown	Not Reported

Naprosyn	C	Unknown	As Necessary		Not Reported
Prednisone	C	Unknown			Not Reported
Ramipril	C	Unknown			Not Reported
Vitamin D	C	Unknown			Not Reported
Naproxen	C	Unknown			Not Reported
Asa Arthritis Strength Aspirin	C	Unknown	Strength: 81 Mg		Not Reported
Ergocalciferol	C	Unknown			Not Reported
Vitamin D3	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12696569	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1473		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Abnormal Loss Of Weight; Adverse Drug Reaction;	Methotrexate (Trade Name Unknown)			S				Not Reported
Arthropathy; Deafness; Deafness Transitory;	Methotrexate (Trade Name Unknown)			S				Not Reported
Decreased Appetite; Dizziness; Drug	Methotrexate (Trade Name Unknown)			S				Not Reported
Hypersensitivity; Ear Infection; Eating Disorder;	Enbrel			S	Subcutaneous			Not Reported
Feeding Disorder; Foot Operation; Functional	Enbrel			S	Unknown			Not Reported
Gastrointestinal Disorder; Gastrointestinal Disorder;	Enbrel			S	Unknown			Not Reported
Gastrointestinal Pain; Headache; Hypophagia;	Enbrel			S	Unknown			Not Reported
Musculoskeletal Disorder; Nausea; Off Label Use;	Motrin			S	Unknown			Not Reported
Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Motrin			S				Not Reported
	Motrin			S				Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported

Arava	S		Not Reported
Arava	S		Not Reported
Aspirin	S	Unknown	Not Reported
Aspirin	S		Not Reported
Aspirin	S		Not Reported
Aspirin	S		Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S		Not Reported
Humira	S		Not Reported
Humira	S		Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Naprosyn	S	Unknown	Not Reported
Naprosyn	S		Not Reported
Naprosyn	S		Not Reported
Naprosyn	S		Not Reported
Gold	S	Unknown	Not Reported
Gold	S		Not Reported
Gold	S		Not Reported
Gold	S		Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S		Not Reported
Plaquenil	S		Not Reported
Voltaren	S	Unknown	Not Reported
Voltaren	S		Not Reported
Voltaren	S		Not Reported
Voltaren	S		Not Reported
Acetylsalicylic Acid	S	Unknown	Not Reported
Acetylsalicylic Acid	S		Not Reported
Acetylsalicylic Acid	S		Not Reported
Acetylsalicylic Acid	S		Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Diclofenac	S	Unknown	Not Reported
Diclofenac Potassium	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported

Sodium Aurothiomalate	S	Oral	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
Vitamin C	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Clopidogrel	S	Unknown	Not Reported
Trimethoprim	S	Unknown	Not Reported
Apo Hydroxychloroquine	S	Unknown	Not Reported
Apo Asa	S	Unknown	Not Reported
Tramadol	S	Unknown	Not Reported
Tramadol Hydrochloride	S	Unknown	Not Reported
Apo-Sulfatrim	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Ibuprofen	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Naproxen	S	Unknown	Not Reported
Sulfatrim	S	Unknown	Not Reported
Asa	S	Unknown	Not Reported
Gold Sodium Thiomalate	S	Unknown	Not Reported
Acetylsalicylic Acid-Clopidogrel	S	Unknown	Not Reported
Acetylsalicylic Acid-Clopidogrel	S		Not Reported
Acetylsalicylic Acid-Clopidogrel	S		Not Reported
Acetylsalicylic Acid-Clopidogrel	S		Not Reported
Tramadol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12701557	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Pain In Extremity; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported

	Apo-Leflunomide	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Meloxicam	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	12957589	EXPEDITED (15-DAY)		CA, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-093145			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Off Label Use; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram,Every One Day		Not Reported
	Naprosyn [Naproxen]			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	500 Mg, Bid		Not Reported
	Erythromycin			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	13107798	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-0119		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Loss Of Personal Independence In Daily Activities; Pain; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Apo Hydroxychloroquin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Methyl Salicylate			S	Unknown			Not Reported
	Salicylates Nos			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

	Apo-Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	13929653	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2698		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown	Dose: 730		Not Reported
	Enbrel			S	Unknown	Dose: 731		Not Reported
	Enbrel			S	Unknown	Dose: 4 Year		Not Reported
	Humira			S	Subcutaneous	Dose: 5 Month		Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Cimzia	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Imuran	C	Unknown	Not Reported
	Vitamin D	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	14223525	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021445		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	1 Df, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5.0 Mg, Bid		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Sulfasalazine	S			Not Reported
Valsartan	C	Unknown	320 Mg, Qd	Not Reported
Xalatan	C	Unknown	50 Mg, Qd	Not Reported
Xalatan	C	Ophthalmic	50 Mg, Qd	Not Reported
Xalatan	C	Unknown	Unk	Not Reported
Xalatan	C	Unknown	50 Mg, Unk	Not Reported
Xalatan	C	Unknown	5.0 Mg, Unk	Not Reported
Dorzolamide + Timolol Genoptim	C	Unknown	Unk, Bid	Not Reported
Estradiol	C	Unknown	6 %, Tid	Not Reported
Furosemide	C	Unknown	40 Mg, Qd	Not Reported
Ergocalciferol	C	Unknown	Unk, Q.Wk.	Not Reported
Estrogel	C	Unknown	0.6 %, Tid	Not Reported
Morphine	C	Unknown	Unk	Not Reported
Morphine	C			Not Reported
Potassium Chloride	C	Unknown	1500 Mg, Qd	Not Reported
Zingiber Officinale	C	Oral	500 Mg, Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Atasol /00020001/	C	Unknown	Unk	Not Reported
Baclofen	C	Unknown	10 Mg, Bid	Not Reported
Calcium	C	Unknown	500 Mg, Unk	Not Reported
Calcium Gluconate	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Levaquin	C	Unknown	500 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	14634541	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1464		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Methotrexate (Trade Name			S	Oral			Not Reported

Drug Ineffective; Drug Intolerance; Drug Resistance; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Unknown) Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S	Unknown	Therapy Duration: 730	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Sodium Aurothiomalate	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Remicade	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	14746351	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009116		50 YR	Female	CAN

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

Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S			Apotex
	Leflunomide	S	Unknown	Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Supeudol	C	Unknown	Unk	Not Reported
	Supeudol	C	Unknown	5 Mg, Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	14782027	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1172			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

U.S. FOOD & DRUG ADMINISTRATION

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	14917342	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-049997			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Burning Sensation; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	750 Milligram, Q4wk		Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Every 10 Days		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Q4wk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Kevzara			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rituximab			S	Subcutaneous			Not Reported

	Tofacitinib Citrate	S	Unknown		Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	15399919	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083462			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Off Label Use; Pain; Peripheral Swelling; Rash; Skin Ulcer	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	15400531	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083802			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Arthropathy; Blood Cholesterol Increased; Gastric Disorder; Granuloma; Off Label Use; Pain In	Orencia			S	Unknown			Bristol Myers Squibb
	Celebrex			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Extremity; Pruritus; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Skin Wrinkling; Spinal Osteoarthritis; Therapeutic Product Effect Decreased; Thyroid Disorder	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	15589215	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3173			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Contraindicated Product Administered; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported

	Otezla	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Sirukumab	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Morphine Sulfate	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	15688989	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1053		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alanine Aminotransferase Increased; Alopecia; Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Aspartate Aminotransferase Increased; Asthenia; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Blood Pressure Fluctuation; Body Temperature Decreased; Bone Density Abnormal; C-Reactive Protein Increased; Chills;	Methotrexate (Trade Name Unknown)			S	Oral	Lower Doses Initially And Increased Over The Years Around 1997		Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Contraindicated Product Administered; Cough;	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Deafness; Decreased Appetite; Disability; Drug	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Eruption; Drug Ineffective; Drug Intolerance; Drug	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Tolerance; Drug Tolerance Decreased; Fatigue;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Gastric Disorder; Granuloma Skin;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Headache; Hypercalcaemia;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Hypercholesterolaemia; Hypersensitivity; Infection;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Inflammation; Insomnia; Limb Deformity; Loss Of	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Personal Independence In Daily Activities; Malaise;	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Mood Swings; Musculoskeletal Pain;	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
Musculoskeletal Stiffness; Nasopharyngitis; Nausea;	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
Neck Mass; Oropharyngeal Pain; Pain;	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
Pain In Extremity; Panniculitis; Peripheral	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
Swelling; Product Use Issue; Product Use Issue;	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
Pyrexia; Rash; Rash Pruritic; Red Blood Cell	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Sedimentation Rate Increased; Rheumatoid	Methotrexate (Trade Name Unknown)	S	Oral		Not Reported
Arthritis; Rheumatoid Nodule; Rosacea; Skin	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Necrosis; Skin Ulcer; Somnolence; Stress;	Methotrexate (Trade Name Unknown)	S	Oral	Strength: 2.5 Mg	Not Reported
Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect	Methotrexate (Trade Name Unknown)	S	Unknown	Lower Doses Initially And Incrased Over The Years Around 1997	Not Reported
Incomplete; Therapeutic Response Decreased; Ulcer; Vomiting; Weight	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported

Increased	Methotrexate (Trade Name Unknown)	S	Subcutaneous	25	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	2x/Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Indocid	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported

Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown	20	Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown	5 Days Out Of 7	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Indomethacin	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Gold (198 Au) Colloidal	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported

Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Codeine	S	Unknown		Not Reported
Alendronate	S	Unknown		Not Reported
Alendronate	S	Unknown		Not Reported
Alendronate	S	Unknown		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Intramuscular	Cyclic	Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Oral		Not Reported
Rituximab	S	Unknown		Not Reported
Alendronic Acid	S	Unknown		Not Reported

Cimzia	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Celebrex	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Naproxen	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Fosamax	S	Unknown		Not Reported
Acetaminophen	S	Oral		Not Reported
Benadryl	S	Oral		Not Reported
Methylprednisolone Sodium Succinate	S	Intravenous (not otherwise specified)		Not Reported
Cymbalta	C	Oral	Nightly	Not Reported
Folic Acid	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Cyclosporine	C	Unknown		Not Reported
Cyclosporine	C	Unknown		Not Reported
B Complex	C	Unknown		Not Reported
Fish Oil	C	Unknown		Not Reported
Ciprodex	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	15979301	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-014058		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rheumatoid Arthritis;	Abatacept			S	Unknown	Unk		Bristol Myers Squibb

Therapeutic Product Effect Incomplete	Rituxan	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6wk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown	200 Mole, Bid	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
	Enbrel	S	Unknown	25 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Sulfasalazine	C	Unknown	1 Gram, Bid	Not Reported
	Wellbutrin	C	Unknown	Unk, Tablet Extended Release	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	16095151	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2710698-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass	C		Not Reported
	Amoxil	C		Not Reported
	Amoxicillin And Clavulanate Potassium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	16200433	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1110		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Blood Pressure Increased; C-Reactive Protein	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Abnormal; Condition Aggravated;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Contraindicated Product Administered; Drug	Methotrexate (Trade Name Unknown)			S	Subcutaneous	2.5 Mg/Ml		Not Reported
Ineffective; Drug Intolerance; Fatigue;	Methotrexate (Trade Name Unknown)			S	Subcutaneous	4 Every 1 Week		Not Reported
Femur Fracture; Gait Disturbance; Gastric	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
Disorder; Glycosylated Haemoglobin Increased;	Enbrel			S	Unknown			Not Reported
Heart Rate Increased;	Enbrel			S	Unknown			Not Reported
Hepatic Enzyme Increased; Infection; Joint	Enbrel			S	Unknown			Not Reported
Swelling; Loss Of Personal Independence In	Enbrel			S	Unknown			Not Reported
Daily Activities;	Enbrel			S	Unknown			Not Reported

Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Neutrophil Count Increased; Osteopenia; Pain; Pain In Extremity; Peripheral Swelling; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence; Synovitis; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Enbrel	S	Unknown	Four Every One Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Four Every One Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	4 Every 1 Week	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Unknown		Not Reported

Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Subcutaneous	Not Reported
Tylenol	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Acetaminophen	S	Unknown	Not Reported
Acetaminophen	S	Oral	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Acetaminophen	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Acetaminophen And Codeine Phosphate	S	Unknown	Not Reported
Apo-Hydro	S	Unknown	Not Reported
Acetaminophen W/Diphenhydramine	S	Unknown	Not Reported

Hydrochloride			
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo Sulfasalazine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Amaryl	S	Unknown	Not Reported
Otezla	S	Unknown	Not Reported
Stelara	S	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported
Tylenol With Codeine No.3	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Hydromorphone Hcl	C	Unknown	Not Reported
Acetaminophen W/Codeine Phosphate	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Glyburide	C	Unknown	Not Reported
Hydrochlorothiazide	C	Unknown	Not Reported
Lipitor	C	Unknown	Not Reported
Metformin	C	Unknown	Not Reported
Methylprednisolone	C	Unknown	Not Reported
Percocet	C		Not Reported
Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	16507983	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Ill-Defined Disorder; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Cyclic		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Actonel	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Risedronate	S	Unknown		Not Reported
Risedronate	S	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	16850467	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019413433			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; White Blood Cell Count Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Tofacitinib			S	Unknown	5 Milligram, Bid		Pfizer
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	16854475	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3626		53 YR	Female	CAN

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

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil Sulfate	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17240411	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026873		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid (Therapy Duration: 730)		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Remicade	S	Unknown	Unk		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Bactrim	S	Unknown	Unk		Not Reported
Cimzia	S	Subcutaneous	Unk		Not Reported
Cimzia	S	Unknown	Unk		Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17334290	EXPEDITED (15-DAY)		HO	JP-ADVANZ PHARMA-202001000333			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17394928	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0702			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Feeling Abnormal; Rheumatoid Arthritis; Thirst; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17404343	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019507572		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Blood Creatinine Increased; Bone Pain; Decreased Appetite; Drug Ineffective; Dyspnoea; Feeling Hot; Heart Rate Decreased; Loss Of Personal Independence In Daily Activities; Macular Degeneration	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, Unk		Not Reported
	Shingrix			S		Unk		Not Reported
	Nitro [Glyceryl Trinitrate]			C	Topical	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17411576	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-202001000165			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Transplacental	200 Mg, Qd (Film Coated Tablet)		Concordia
	Predonine			C		Unk		Not Reported
	Tracleer Dt			C		Unk		Not Reported
	Berasus			C		Unk		Not Reported
	Baktar			C		Unk		Not Reported
	Minocycline Hydrochloride			C		Unk		Not Reported
	Alprostadil			C		Unk		Not Reported
	Rebamipide			C		Unk		Not Reported

Nexium 1-2-3	C	Unk	Not Reported
Sucralfate	C	Unk	Not Reported
Ritodrine	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17416504	NON-EXPEDITED		HO	US-ACTELION-A-US2020-201797		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacteraemia; Blood Culture Positive; Brevibacterium Infection; Catheter Management; Catheter Site Infection; Device Related Infection; Ear Infection; Immunosuppression; Sepsis	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Veletri			S	Intravenous (not otherwise specified)	28 Ng/Kg, Per Min		Actelion
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Letairis			C				Not Reported
	Xarelto			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17448570	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0942			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Neutropenia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Sarilumab			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17448571	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		53 YR	Male	CAN

PHARMA-TREX2020-0941

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colon Neoplasm; Psoriasis; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17448674	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201905-001299			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium; Retinal Depigmentation; Visual Field Defect	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17448792	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-012554		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449079	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-00768		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypertrophic Cardiomyopathy; Overdose; Thrombocytopenia	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Lupin
	Metoprolol			C	Unknown	Unk		Not Reported
	Losartan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449110	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP026903			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Crohn'S Disease; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Sinusitis; Urosepsis	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, 1 Every 4 Weeks		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Certolizumab Pegol			C	Unknown	400 Mg, Q.O.Wk.		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported
	Tocilizumab			C	Unknown	8.0 Mg/Kg, (One Evey Four Weeks)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449159	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188424		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haematochezia	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown	20 Mg		Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449167	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil[Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449227	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552826		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449309	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020073056			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Gastrointestinal Disorder; Hepatitis; Rash	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		50 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449310	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020073493			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Hepatotoxicity; Nausea; Therapeutic Response Decreased; Transaminases Increased	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
	Sulfasalazine			S		1000 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S		300 Mg, 1x/Day		Not Reported
	Leflunomide			S	Oral	10 Mg, 1x/Day		Not Reported
	Levothyroxine Sodium			S	Oral	0.075 Ug, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Azathioprine			C		50 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449466	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188414			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Acetaminophen			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Teva
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown	200 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449547	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000942			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriasis	Hydroxychloroquine			S		Unk		Concordia
	Prednisone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17449615	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188475		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Prednisone			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Simponi	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Golimumab	S	Unknown		Not Reported
	Salazopyrin	C	Unknown		Not Reported
	Diclofenac	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17450164	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0964		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Rabeprazole Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17450354	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555260		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17450653	EXPEDITED (15-DAY)		HO, OT	US-APPCO PHARMA LLC-2080818		11 YR	Female	USA

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

Gastroenteritis Cryptosporidial; Hypogammaglobulinaemia ; Leukopenia; Neutropenia	Hydroxychloroquine Sulfate	S	Unknown	Appco Pharma
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17450830	EXPEDITED (15-DAY)		HO, LT, OT	PT-UNITED THERAPEUTICS-UNT-2020-002924			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Cardiogenic Shock; Serositis	Remodulin Sq			S	Subcutaneous	0.046 Mg/H, Continuing		United Therapeutics
	Prednisolone			S	Unknown	5 Mg		Not Reported
	Mycophenolate Mofetil			S	Unknown	2.5 G		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Bosentan			S	Unknown	250 Mg		Not Reported
	Riociguat			C	Unknown	6 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17450973	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555709		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

Methotrexate	C	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported
Tylenol With Codeine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451026	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-012586			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451038	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020075510			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Empyema; Musculoskeletal Stiffness; Pain	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Oral	Unk, 1x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg/Kg, 1 Every 12 Hours		Pfizer
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported
	Leflunomide			S	Oral	10 Mg, 1x/Day		Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451060	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020075442		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	2 G, Every Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Every Day		Not Reported
	Orencia			S	Unknown	125 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451063	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020075503			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	1000 Mg, 2x/Day		Pfizer
	Atorvastatin Calcium			S	Oral	40 Mg, 1x/Day		Pfizer
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Oral	400 Mg, 1x/Day		Not Reported
	Acetaminophen			C	Oral	500 Mg, Unk		Not Reported
	Asa Ec			C	Oral	81 Mg, 1x/Day		Not Reported
	Folic Acid			C	Oral	5 Mg, Weekly		Not Reported
	Vitamin D3			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451087	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020075507		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Codeine			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Adalimumab			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451102	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020075437			Female	CAN

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

Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypersensitivity Vasculitis; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Rash; Respiratory Tract Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel	S	Subcutaneous	50 Mg, Weekly		Pfizer
	Sulfasalazine	S	Unknown	500 Mg, Unk		Pfizer
	Xeljanz	S	Oral	50 Mg, 2x/Day		Pfizer
	Actemra	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Mg, Unk		Not Reported
	Atenolol	C	Unknown	Unk		Not Reported
	Celebrex	C	Unknown	Unk		Not Reported
	Colchicine	C	Unknown	Unk		Not Reported
	Coversyl [Perindopril Arginine]	C	Unknown	Unk		Not Reported
	Hctz	C	Unknown	Unk		Not Reported
	Leucovorin [Calcium Folinate]	C	Oral	5 Mg, Weekly		Not Reported
	Levothyroxine Sodium	C	Unknown	Unk		Not Reported
	Methotrexate	C	Intramuscular	12.5 Mg, Weekly		Not Reported
	Ranitidine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451130	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020077701		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Intolerance; Haematochezia; Joint Swelling; Neuropathy Peripheral; Rash; Skin Burning Sensation	Sulfasalazine			S	Unknown	1000 Mg, 1 Every 12 Hours		Pfizer
	Sulfasalazine			S	Unknown	1000 Mg, 1 Every 12 Hours		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported
	Acetaminophen			C	Oral	500 Mg, Unk		Not Reported
	Asa Ec			C	Oral	81 Mg, 1x/Day		Not Reported

Atorvastatin	C	Oral	40 Mg, 1x/Day		Not Reported
Folic Acid	C	Oral	5 Mg, Weekly		Not Reported
Leflunomide	C	Unknown	20 Mg, Unk		Not Reported
Vitamin D3	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451149	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020077712			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Colchicine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Januvia			S		Unk		Not Reported
	Metformin			S	Unknown			Not Reported
	Actemra			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451169	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020077721			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Nausea; Neuropathy Peripheral	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Sulfasalazine			S	Oral	1 G, 2x/Day, Every 12 Hours		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Daily		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular	80 Mg, 1 Every 2 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451236	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-012595			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Intravenous (not otherwise specified)	20 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451321	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552800		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Mefenamic Acid	C		Not Reported
	Prednisone	C		Not Reported
	Tylenol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17451388	NON-EXPEDITED			US-PFIZER INC-2020076679		67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Feeling Abnormal; Oedema Peripheral	Xeljanz			S	Oral	5 Mg, 2x/Day (5 Mg One Tablet By Mouth Twice A Day)		Pfizer
	Lyrica			S		Unk, 3x/Day		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Prednisone			S		5 Mg, Alternate Day (Every Other Day)		Not Reported
	Prednisone			S		5 Mg, Alternate Day		Not Reported
	Plaquenil			S		Unk		Not Reported
	Hydrochlorothiazide			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Methotrexate Sodium			S	Oral	5 Mg, Weekly (2.5 Mg Two Tablet By Mouth One Time A Week)		Not Reported
	Orencia			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452006	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020075115		70 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Lampren			S	Oral	100 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	1 Df, 1x/Day		Not Reported
	Noxafil			S	Oral	300 Mg, 1x/Day		Not Reported
	Cholurso			C				Not Reported
	Propranolol			C				Not Reported
	Ethambutol Hydrochloride			C				Not Reported
	Pantoprazole			C				Not Reported
	Tramadol			C				Not Reported
	Aldactone [Spironolactone]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452106	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1018551		23 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Chest Pain; Respiratory Distress; Tachycardia; Unevaluable Event	Escitalopram			S		Unk		Not Reported
	Plaquenil /00072602/			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452218	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020077853		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Faeces Discoloured; Fibromyalgia; Gait Disturbance; General	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	1 Df, Weekly		Pfizer
	Methotrexate Sodium			S				Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Unknown
	Methotrexate Sodium			S				Unknown
	Sulfasalazine			S	Oral	2 G, 1x/Day		Pfizer

Physical Health Deterioration; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Malaise; Meniscus Injury; Neuropathy Peripheral; Off Label Use; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Paraplegia; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Disorder; Spinal Stenosis; Treatment Failure; Upper Respiratory Tract Infection	Aclasta	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Unknown	20 Mg, 1 Every 1 Day	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 1 Every 1 Day	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Leflunomide	S	Unknown	20 Mg, 1 Every 1 Day	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S			Not Reported
	Tramacet	S	Oral		Not Reported
	Tramacet	S	Unknown	Unk	Not Reported
	Amitriptyline	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Depo-Medrol	C	Subcutaneous	Unk Unk, Monthly	Not Reported
	Depo-Medrol	C	Intramuscular		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Lorazepam	C	Unknown	1 Mg, 1 Every 1 Day	Not Reported
	Lyrica	C	Oral	150 Mg, 2 Every 1 Day	Not Reported
	Metformin	C	Unknown	5 Mg, 1 Every 1 Day	Not Reported
	Metformin	C		500 Mg, 2 Every 1 Day	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Mg, Monthly	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	40 Mg, Monthly	Not Reported

Methylprednisolone Acetate	C	Subcutaneous	Unk, Monthly	Not Reported
Methylprednisolone Acetate	C	Unknown		Not Reported
Nortriptyline	C	Unknown	2 Df, Unk	Not Reported
Nortriptyline	C			Not Reported
Nortriptyline	C	Unknown		Not Reported
Nortriptyline	C			Not Reported
Nortriptyline Hydrochloride	C	Unknown	20 Mg, 1x/Day	Not Reported
Nortriptyline Hydrochloride	C			Not Reported
Nortriptyline Hydrochloride	C	Unknown		Not Reported
Nortriptyline Hydrochloride	C			Not Reported
Oxycocet	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Premarin	C	Unknown	0.625 Mg, Unk	Not Reported
Risedronate Sodium	C	Unknown	35 Mg, Weekly	Not Reported
Tylenol 8 Hr Arthritis Pain	C	Unknown		Not Reported
Vagifem	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452244	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020071737		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Blood Pressure Increased; Blood Pressure Systolic Increased; Cataract; Decreased Appetite; Dizziness; Dyspepsia; Heart Rate Decreased; Nausea; Rheumatoid Arthritis; Vomiting; Weight Decreased; Weight Increased	Sulfasalazine			S	Unknown			Pfizer
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Acetaminophen			C	Oral	650 Mg, Unk		Not Reported
	Atorvastatin			C				Not Reported
	Benadryl			C	Oral	50 Mg, Unk		Not Reported
	Cymbalta			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Irbesartan			C				Not Reported
	Lipitor			C	Unknown			Not Reported

Prednisone	C				Not Reported
Solu-Medrol	C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
Tramadol	C	Unknown	Unk Unk, As Needed		Not Reported
Vitamin D3	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452265	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188323			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Infection; Pneumonia	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S	Intra-arterial			Barr
	Prednisone			S	Unknown			Actavis
	Naproxen Sodium			S	Unknown			Teva
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452272	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187850		71 YR	Female	CAN

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

Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis	Prednisone	S	Unknown	Actavis
	Acetaminophen	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Dilaudid	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452273	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187784			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Tocilizumab			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452285	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Fatigue; Malaise	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Folate			S	Unknown			Not Reported
	Prevacid			C				Not Reported
	Risedronate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17452569	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2020074362		68 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diffuse Large B-Cell Lymphoma Stage I	Sulfasalazine			S		1 G, 3x/Day (En)		Pfizer
	Hydroxychloroquine			S		200 Mg, 1x/Day		Not Reported
	Diclofenac			C		Unk, As Needed		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17453023	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188503			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Affective Disorder; Arthralgia; Depression; Drug Ineffective; Frequent Bowel Movements; Gastric Disorder; Glaucoma; Joint Swelling; Musculoskeletal	Prednisone			S	Unknown	25 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Folic Acid			S	Unknown			Not Reported

Stiffness; Nausea; Psoriasis	Humira		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Methotrexate		S	Oral	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17453996	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188808		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Eliquis Film Coated			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Xeljanz			S	Oral	5 Milligram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17453997	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188754			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Bowel Movement Irregularity; Depression; Gastric Disorder; Glaucoma; Nausea; Psoriasis; Treatment Failure	Prednisone			S	Unknown	25 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	2.1429 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Varicella Zoster Vaccine Live			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2020	17454177	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-013596			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Intra-arterial	25 Milligram, Qd		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	9426564	EXPEDITED (15-DAY)		HO, OT	US-SANOFI-AVENTIS-2013SA075840		41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Balance Disorder; Cervical Radiculopathy; Condition Aggravated; Contusion; Cutaneous Lupus Erythematosus; Dehydration; Depressed Mood; Depression; Diarrhoea; Fatigue; Gastritis; Gastroenteritis Viral; Grip Strength Decreased; Headache; Hot Flush; Limb Discomfort; Multiple Sclerosis Relapse; Nausea; Rash; Spinal Pain; Toothache; Vision Blurred; Visual Impairment	Teriflunomide			S	Oral	7 Mg,Qd		Sanofi
	Teriflunomide			S	Oral	14 Mg,Qd		Sanofi
	Plaquenil			S				Sanofi
	Cymbalta			C	Unknown	90 Mg,1x		Not Reported
	Cymbalta			C				Not Reported
	Ritalin			C	Unknown	5 Mg,1x		Not Reported
	Orsythia			C		28 U, 1x		Not Reported
	Omeprazole			C	Unknown	20 Mg,1x		Not Reported
	Vitamin D3			C	Unknown	1000 Iu,1x		Not Reported
	Cyanocobalamin			C	Unknown	2000 Ug,1x		Not Reported
	Trazodone			C	Unknown	100 Mg,1x		Not Reported
	Trazodone			C				Not Reported
	Zanaflex			C	Unknown	4 Mg,1x		Not Reported
	Carbamazepine			C	Unknown	300 Mg,Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	11115474	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1389528-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Anakinra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	11618838	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1476816-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Loss Of Consciousness; Mobility Decreased; Mobility Decreased; Musculoskeletal Disorder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	12253776	EXPEDITED (15-DAY)		DS	CA-ABBVIE-16K-028-1600446-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	13118364	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELLTRION INC.-2015CA012467			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported

Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Intolerance; Enthesopathy; Erythema; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder;	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Times/Wk	Not Reported
	Enbrel	S		25 Milligram	Not Reported
	Enbrel	S		Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	20 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Ibuprofen	S	Oral	600 Mg, Every 3-4 Hours Regularly	Not Reported
	Ibuprofen	S	Oral	600 Mg, Q4h	Not Reported
	Ibuprofen	S	Oral	600 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	Unk Unk (4.0 Dosage Forms), Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	2.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	17.5 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	12 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	10 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	2.5 Milligram, Qmo	Not Reported
	Methotrexate Sodium	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	7.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	10 Milligram, 4 Times/Wk	Not Reported
	Celebrex	S	Oral	200 Milligram, Bid	Not Reported

Treatment Failure; Ulcer; Urticaria	Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, 4 Times/Wk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Milligram, 4 Times/Wk	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Cosentyx	S	Subcutaneous	300 Milligram, Qmo	Not Reported
	Apo Ibuprofen	S	Oral	600 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Cyclosporine	S	Oral	Unk	Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Golimumab	S	Subcutaneous	Unk (Solution)	Not Reported
	Ustekinumab	S	Subcutaneous	Unk	Not Reported
	Ustekinumab	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Certolizumab Pegol	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Apremilast	S	Oral	30 Mg, 2x/Day	Not Reported

Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	60 Mg, Bid	Not Reported
Cyclosporin	S	Oral	Unk	Not Reported
Cyclosporin	S	Unknown	Unk	Not Reported
Otezla	S	Oral	30 Mg, Bid	Not Reported
Otezla	S		Unk	Not Reported
Otezla	S		Unk	Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Oral	600 Mg, Unk	Not Reported
Motrin	S	Oral	600 Mg, Every 3-4 Hours Regularly	Not Reported
Motrin	S	Oral	600 Mg, Q4h	Not Reported
Motrin	S	Oral	600.0 Mg, Unk	Not Reported
Motrin	S		6 Df, 1x/Day	Not Reported
Motrin	S	Oral	600 Milligram, Qd	Not Reported
Motrin	S	Oral	Unk, Qd	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Milligram 4 Every One Week	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not	Unk	Not Reported

		otherwise specified)		
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Oxyneo	C	Unknown	10 Mg, Unk	Not Reported
Oxyneo	C	Unknown	40 Mg, Unk	Not Reported
Mogadon	C	Unknown	5 Mg, Unk	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day (Freq: 2 Day; Interval: 1)	Not Reported
Uloric	C	Oral	80 Mg, 2x/Day	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C		80 Mg, Bid	Not Reported
Uloric	C	Unknown	Unk Mg, Unk	Not Reported
Uloric	C	Oral	8 Milligram, Bid	Not Reported
Colchicine	C	Oral	0.6 Milligram	Not Reported
Colchicine	C	Oral	6 Milligram	Not Reported
Acide Folique	C		Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nitrazepam	C	Unknown	5 Mg, Unk	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C		50 Milligram	Not Reported
Oxycodone	C	Unknown	40 Mg, Unk	Not Reported
Oxycodone	C	Unknown	10 Mg, Unk	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	80 Mg, Bid	Not Reported
Methotrexate Sodium	C	Oral	Unk, 1/Week	Not Reported

Methotrexate Sodium	C		2.5 Milligram 4 Tablets, Once A Week	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Mg, Unk	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Mg, Unk	Not Reported
Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
Prednisone	C		Unk	Not Reported
Xeljanz	C		Unk	Not Reported
Naproxen	C		500 Milligram	Not Reported
Cannabis Sativa	C		Unk	Not Reported
Actonel	C	Oral	35 Milligram, Qwk	Not Reported
Vitamin D 3	C	Oral	2000 International Unit	Not Reported
Risedronate Sodium	S	Oral	35 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	13516208	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037950		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Off Label Use; Platelet Count Decreased; Respiratory Tract Infection Viral; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Phosphate			S	Unknown	200 Mg, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Etanercept			S	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported

Folic Acid	C	Unknown			Not Reported
Ketorolac	C	Unknown			Not Reported
Methotrexate	C	Unknown	20 Mg, Qwk		Not Reported
Naproxen	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	13525808	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1965986-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	13537999	EXPEDITED (15-DAY)		HO, LT	CA-ABBVIE-17K-028-1972796-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported

Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	14138176	EXPEDITED (15-DAY)		OT	CA-SA-2014SA144669		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Pneumonia; Synovitis	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Intra-articular	Unk Unk,Unk		Not Reported

	Methotrexate	S	Intra-arterial	Unk Unk,Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk Unk,Unk	Not Reported
	Celecoxib	S	Unknown	Unk Unk,Unk	Not Reported
	Prednisone	S	Unknown	5 Mg,Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Enbrel	S	Subcutaneous	Unk Unk,Qw	Not Reported
	Gold	S	Unknown	Unk Unk,Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg,Qw	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	14235931	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3893		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

Xeljanz	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Azathioprine	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Minocycline	S	Unknown		Not Reported
Minocycline	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Oral		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Apo-Minocycline	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400	Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Leflunomide	C	Unknown	20 Unk	Not Reported
	Leflunomide	C	Unknown		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Hydroxychloroquine	C	Subcutaneous		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Amoxil	C	Unknown		Not Reported
	Bcg Vaccine	C	Unknown		Not Reported
	Gold	C	Unknown		Not Reported
	Clavulin	C	Unknown		Not Reported
	Clavulin	C	Unknown		Not Reported
	Amoxicillin Trihydrate And Clavulante Potass	C	Unknown		Not Reported
	Adalimumab	C	Unknown		Not Reported
	Risedronate	C	Unknown		Not Reported
	Amoxicillin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	14408887	EXPEDITED (15-DAY)		HO, LT	CA-ABBVIE-18K-028-2225316-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

Apo-Leflunomide	S	Unknown			Not Reported
Apo-Leflunomide	S				Not Reported
Enbrel	S	Unknown			Not Reported
Enbrel	S				Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine	S				Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S				Not Reported
Ilaris	S	Subcutaneous	Single-Use Vial Powder For Solution		Not Reported
Ilaris	S				Not Reported
Methotrexate	S	Unknown			Not Reported
Methotrexate	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
Remicade	S				Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S				Not Reported
Leflunomide	S	Unknown			Not Reported
Leflunomide	S				Not Reported
Methotrexate Sodium	S	Unknown			Not Reported
Plaquenil	S	Unknown			Not Reported
Plaquenil	S				Not Reported
Sulfasalazine	S	Unknown			Not Reported
Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	14532984	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ABBVIE-18K-028-2254850-00			Male	CAN

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

Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15146837	EXPEDITED (15-DAY)		OT	CA-ROCHE-2150829		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Drug Ineffective; Dyspepsia; Gastric Disorder; Gastric Disorder; General Physical Health Deterioration; Insomnia; Nausea; Rheumatoid Arthritis	Tocilizumab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown	Therapy Duration: 5 Months		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Ustekinumab			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Orencia			C	Unknown	Therapy Duration: 4 Years		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15395225	NON-EXPEDITED			US-PFIZER INC-2018371106		44 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15543164	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016253265		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Off Label Use; Pneumonia; Prescribed Underdose; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk (Powder And Solvent For Solution For Injection/Infusion)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

	Prednisone	C	Unknown	5 Mg, 1x/Day (Every 24 Hours)	Not Reported
	Prednisone	C	Unknown	10 Mg, 2x/Day	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15712130	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588065-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Mefenamic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C				Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15715888	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588290-00		51 YR	Male	CAN

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

Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15716038	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587979-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15880483	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2019002469			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		162 Milligram		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Imuran			C	Subcutaneous	50 Mg, Once Daily (Qd)		Not Reported
	Azathioprine			C	Subcutaneous	50 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Remicade			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15939703	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2658273-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15939769	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2658337-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	C			Not Reported
	Wellbutrin	C	Unknown	Extended Release Tablet	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15941600	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2658637-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Urticaria; Wrist Surgery	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Rocuronium			S	Unknown			Not Reported

	Prednisone	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15941848	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2659005-00		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15978220	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013626			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Uveitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	40 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	10 Milligram		Not Reported
	Cimzia			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	15993853	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2672993-00		59 YR	Female	CAN

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

Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Clonazepam	C	Oral	Not Reported
	Asa	C		Not Reported
	Nitroglycerin	C		Not Reported
	Gabapentin	C	Oral	Not Reported
	Desipramine	C		Not Reported
	Rosuvastatin Calcium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	16174468	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2736324-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

	Sulfasalazine	C			Not Reported
	Wellbutrin	C		Tablet (Extendedrelease)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	16284690	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019017151		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication; Psoriatic Arthropathy; Rheumatoid Arthritis; Uveitis	Cimzia			S	Subcutaneous			Ucb
	Cosentyx			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S		Unk		Not Reported
	Remicade			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S		Unk, Once Daily (Qd)		Not Reported
	Sulfasalazine			S		2 Gram		Not Reported
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		400 Milligram		Not Reported
	Methotrexate			C	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	16460073	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822502-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Hydro	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	16861198	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3753			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; Unevaluable Event; White Blood Cell Count Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17069514	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-201911001949			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disability; Drug Ineffective	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17370881	EXPEDITED (15-DAY)		DE, HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-004		77 YR	Male	USA

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

Cardiac Arrest; Drug Ineffective; Pancytopenia	Imunoglobulin (Immunoglobulin G Human)	S	Unknown	Not Reported
	Immunoglobulin (Iggiv)	S	Intravenous (not otherwise specified)	Not Reported
	Imunoglobulin (Immunoglobulin G Human)	S		Not Reported
	Dexamethasone	S	Oral	Westward
	Dexamethasone	S		Westward
	Dexamethasone	S		Westward
	Hydroxychloroquine	S	Unknown	Westward
	Bortezomib	S	Intravenous (not otherwise specified)	Not Reported
	Bortezomib	S	Subcutaneous	Not Reported
	Bortezomib	S	Intravenous (not otherwise specified)	Not Reported
	Bortezomib	S	Intravenous (not otherwise specified)	Not Reported
	Bortezomib	S	Intravenous (not otherwise specified)	Not Reported
	Bortezomib	S	Intravenous (not otherwise specified)	Not Reported
	Cyclophosphamide	S	Intravenous (not otherwise specified)	Not Reported
	Cyclophosphamide	S	Intravenous (not otherwise specified)	Not Reported
	Cyclophosphamide	S	Intravenous (not otherwise specified)	Not Reported
	Cyclophosphamide	S	Intravenous (not otherwise specified)	Not Reported
	Thalidomide	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Iron	C	Intravenous (not otherwise specified)	Not Reported

	Tadalafil	C	Unknown	Not Reported
	Ambrisentan	C	Unknown	Not Reported
	Ambrisentan	C	Unknown	Not Reported
	Lasix	C	Unknown	Not Reported
	Rituximab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17416957	EXPEDITED (15-DAY)		DS, OT	US-ADVANZ PHARMA-202002000701			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness; End Stage Renal Disease; Maculopathy; Overdose; Retinopathy	Hydroxychloroquine			S	Unknown	300 Mg, Qd ((6.5 Mg/Kg Actual Body Weightper Day)		Concordia
	Hydroxychloroquine			S	Unknown	400 Mg, Qd (200 Mg Twice Daily,8.2 Mg/Kg Actual Body Weight Per Day)		Concordia
	Hydroxychloroquine			S		400 Mg, Qd (8 Mg/Kg Actual Body Weightunk		Concordia
	Prednisone			C		Unk		Not Reported
	Mycophenolate Mofetil			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454316	EXPEDITED (15-DAY)		OT	CA-ROCHE-2556590		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454391	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555707			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454474	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-013659			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported

	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454489	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-013781			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454580	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000601			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Condition Aggravated; Oedema Peripheral	Hydroxychloroquine			S	Unknown	200 Milligram		Ipca
	Paracetamol			C	Unknown	Take One Or Two Tablets Up To Four Times A Day ...		Not Reported
	Trimbow			C	Respiratory (inhalation)	4 Dosage Form, Qd		Not Reported
	Clenil Modulite			C	Respiratory (inhalation)	4 Dosage Form, Qd		Not Reported
	Terbutaline			C	Respiratory (inhalation)	1 Dosage Form, Prn		Not Reported
	Atorvastatin			C	Unknown	1 Dosage Form, Qd		Not Reported
	Levothyroxine			C	Unknown	1 Dosage Form, Qd		Not Reported
	Prednisolone			C	Unknown	1 Dosage Form, Qd		Not Reported
	Lansoprazole			C	Unknown	1 Dosage Form, Qd		Not Reported
	Alendronic Acid			C	Unknown	1 Dosage Form, Q.W		Not Reported
	Cetirizine			C	Unknown	1 Dosage Form, Qd		Not Reported
	Simvador			C	Unknown	1 Dosage Form, Hs		Not Reported
	Furosemide			C	Unknown	2 Dosage Form, Qd		Not Reported
	Braltus			C	Respiratory (inhalation)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555257		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Rituxan			S	Intravenous (not			Not Reported

Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea; Stress			otherwise specified)	
	Apo-Leflunomide	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Advil [Ibuprofen]	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454626	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0977			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Disorder; Hepatotoxicity; Pain	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454794	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-014130			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Xeljanz			C	Oral	50 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454837	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552651		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

Methotrexate	S	Parenteral		Not Reported
Orencia	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Azathioprine	C			Not Reported
Ciclosporin	C	Unknown		Not Reported
Minocycline	C			Not Reported
Penicillamine	C			Not Reported
Prednisone	C			Not Reported
Actemra	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17454967	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1187769			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455012	NON-EXPEDITED		HO, OT	AU-AMGEN-AUSSP2020029522			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ageusia; Arthralgia; Depression; Dna Antibody Negative; Drug Interaction; Fibromyalgia; Gait Disturbance; Liver Function Test Abnormal; Migraine; Nausea; Panic Attack; Paraesthesia; Psoriasis; Psoriatic Arthropathy; Respiratory Syncytial Virus Infection; Sleep Disorder; Suicidal Ideation; Systemic Lupus Erythematosus; Tachyarrhythmia; Type 1 Diabetes Mellitus; Urinary Tract Infection; Viral Tonsillitis	Ivabradine			S	Unknown	7.5 Milligram, Bid		Amgen
	5-Methyltetrahydrofolate			S	Unknown	Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			S	Unknown	100 Milligram		Not Reported
	Cannabis Sativa Oil			S	Unknown	Unk		Not Reported
	Colecalciferol			S	Unknown	Unk		Not Reported
	Endone			S	Oral	5 Milligram, Qd		Not Reported
	Glucagen [Glucagon Hydrochloride]			S	Unknown	Unk		Not Reported
	Glyceryl Trinitrate			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram 2x A Week		Not Reported
	Mirena			S	Unknown	52 Milligram		Not Reported
	Novorapid			S	Subcutaneous	Unk		Not Reported
	Oxycontin			S	Oral	10 Milligram, Bid		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Prasugrel			S	Unknown	10 Milligram, Qd		Not Reported
	Sildenafil			S	Oral	12.5 Milligram		Not Reported
	Mycophenolate Mofetil			S	Oral	1500 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, 2x A Week		Not Reported
	Methotrexate			S	Unknown	10 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Rosuvastatin			S	Unknown	10 Milligram		Not Reported

Ezetimibe	S	Unknown	10 Milligram		Not Reported
Ramipril	S	Unknown	Unk		Not Reported
Topiramate	S	Unknown	200 Milligram		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Reboxetine	S	Unknown	8 Milligram, Qd		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Prednisolone	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Cyanocobalamin	S	Unknown	Unk		Not Reported
Folic Acid	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455030	EXPEDITED (15-DAY)		OT	GB-EMCURE PHARMACEUTICALS LTD-2015-EPL-0087		69 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Iron Deficiency; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Metformin			S	Unknown	Unk		Heritage
	Humira			S	Unknown	40 Milligram		Not Reported
	Humira			S		Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455416	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1188810			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis; Weight Increased; Wheelchair User	Prednisone			S	Unknown	6.25 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Acetaminophen			S	Unknown			Not Reported
	Indometacin			S	Unknown			Actavis

Arava	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Statex (Morphine Sulfate)	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455636	EXPEDITED (15-DAY)		OT	CA-SA-2020SA044419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haemorrhoids; Rectal Haemorrhage	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			C		Unk		Not Reported
	Tofacitinib			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455822	EXPEDITED (15-DAY)		OT	CA-ROCHE-2556596			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455825	EXPEDITED (15-DAY)		OT	CA-ROCHE-2556141		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

Treatment Noncompliance	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455835	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-084092		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Tramadol Hydrochloride			S	Unknown	Unk		Aurobindo
	Sulfamethoxazole;Trimethoprim			S	Unknown	Unk		Not Reported
	Apo-Diclofenac			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Diclofenac Potassium			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Intracardiac	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Plaquenil			S	Intracardiac	Unk		Not Reported
	Mortin			S	Intracardiac	Unk		Not Reported
	Voltaren			S	Intracardiac	Unk		Not Reported
	Acetylsalicylic Acid;Clopidogrel			S	Intracardiac	Unk		Not Reported
	Sodium Aurothiomalate			S	Intracardiac	Unk		Not Reported

	Diclofenac			S	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455855	EXPEDITED (15-DAY)		OT	CA-ROCHE-2556483			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17455961	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020006941			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Lupus-Like Syndrome; Swelling Face	Cimzia			S	Subcutaneous	Unk		Ucb
	Arava			S				Not Reported
	Methotrexate			S				Not Reported
	Mycophenolate Sodium			S		Unk, 2x/Day (Bid)		Not Reported
	Plaquenil Sulfate			S				Not Reported
	Prednisone			S				Not Reported
	Remicade			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17456198	EXPEDITED (15-DAY)		HO, OT	GB-ADVANZ PHARMA-202002000973			Unknown	GBR

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

Infection; Infective Tenosynovitis; Vasculitic Ulcer	Prednisolone	S	Unk	Concordia
	Prednisolone	S	Reduse	Concordia
	Hydroxychloroquine	S	Unk	Not Reported
	Hydroxychloroquine	S	Increased Dose	Not Reported
	Hydroxychloroquine	S	Reduse	Not Reported
	Azathioprine	S	Unk	Not Reported
	Azathioprine	S	Reduse	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17456353	EXPEDITED (15-DAY)		OT	NVSC2020IN045134		41 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Condition Aggravated; Depressed Level Of Consciousness; Nocardiosis	Methotrexate			S	Unknown	10 Mg, Qw		Not Reported
	Prednisolone			S	Unknown	30 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	200 Unk, Qd		Not Reported
	Sulfamethoxazole And Trimethoprim			C	Intravenous (not otherwise specified)	15 Mg/Kg Divided In Three Doses		Not Reported
	Amikacin			C	Intravenous (not otherwise specified)	7.5 Mg/Kg, Bid		Not Reported
	Meropenem			C	Intravenous (not otherwise specified)	500 Mg Every 6 Hours		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17456398	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019546029		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Fatigue; Lower Respiratory Tract Infection; Off Label Use	Sulfasalazine			S	Unknown	Unk		Pfizer
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17456606	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1189404		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Arthralgia; Blister; Chills; Erythema; Lethargy; Neutrophil Count Increased; Oedema; Pain; Pain Of Skin; Palmar Erythema; Pyrexia; Rash Pruritic; Rash Pustular; Rebound Effect; Skin Exfoliation; Swelling; White Blood Cell Count Increased	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17456924	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1019498		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Varicella Zoster Virus Infection	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Prednisone			S	Unknown	40 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	Tapered Down From 40 Mg/Day To 20 Mg/Day Over The Previous 4 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17457814	EXPEDITED (15-DAY)		HO	CA-UCBSA-2020007174		46 YR	Female	CAN

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

Drug Ineffective; Interstitial Lung Disease	Cimzia	S	Subcutaneous	Unk	Not Reported
	Anakinra	S		Unk	Not Reported
	Enbrel	S			Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Not Reported
	Mycophenolate Mofetil	S		Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Humira	C	Subcutaneous		Not Reported
	Celebrex	C			Not Reported
	Methotrexate	C		1 Milligram, Weekly (Qw)	Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458210	EXPEDITED (15-DAY)		DS	CA-ABBVIE-20K-028-3290536-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Dizziness; Gastrointestinal Disorder; Headache; Hypotension; Joint Noise; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Psoriatic Arthropathy; Rheumatoid Arthritis; Sensitivity To Weather Change; Therapeutic Product Effect Decreased; Vaginal Haemorrhage; Vomiting; Weight	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leucovorin			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C				Not Reported
	Calcium Citrate			C				Not Reported
	Magnesium Citrate Forte			C				Not Reported
	Citalopram Hydrobromide			C				Not Reported
	Clobetasol Propionate			C	Topical			Not Reported

Increased	Escitalopram Oxalate	C	Not Reported
	Naproxen	C	Not Reported
	Pantoprazole Magnesium	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458220	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020006969		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S				Not Reported
	Methotrexate			C				Not Reported
	Orencia			C				Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Otezla			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S				Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Salazopyrin			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sirukumab			S				Not Reported
	Sulfasalazine			S				Not Reported
	Ustekinumab			S				Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458254	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1190225		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Cardiac Failure; Cardiotoxicity; Hypertrophic	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Teva
	Metoprolol			C	Unknown			Not Reported

Cardiomyopathy; Overdose	Losartan		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458528	EXPEDITED (15-DAY)		OT	CA-SA-2020SA045267			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Retinal Toxicity	Leflunomide			S		200 Mg, Qod		Sanofi
	Hydroxychloroquine			S		400 Mg, Qd		Sanofi
	Methotrexate			C	Oral	20 Mg		Not Reported
	Methotrexate			C	Intramuscular	20 Mg		Not Reported
	Sulfasalazine			C		1 G, Bid		Not Reported
	Prednisone			C		Unk		Not Reported
	Asa Ec			C		650 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458535	EXPEDITED (15-DAY)		OT	CA-SA-2020SA045718			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Meningitis; Treatment Failure; Unevaluable Event	Hydroxychloroquine			S	Oral	200 Mg, Qd (1 And 1/2 Tablets)		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Prednisone			S		(On And Off , Last Taken In Jun -2019)		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Actemra			S				Not Reported
	Remicade			S				Not Reported
	Methotrexate			C		20 Mg, Qw		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	9643129	EXPEDITED (15-DAY)		OT	CA-ROCHE-1287733		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Drug Hypersensitivity; Eye Disorder; Fatigue; Fibromyalgia; Infusion Related Reaction; Menopause; Oxygen Saturation Decreased; Pain; Rheumatoid Arthritis; Thermal Burn	Rituxan			S	Intravenous (not otherwise specified)	Most Recent Dose Prior To Sae: 06/May/2010, 17/Jun/2014, 26/Apr/2016		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Effexor			S	Unknown	Dosage Not Specified		Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Arthrotec			C				Not Reported
	Methotrexate			C				Not Reported
	Folic Acid			C				Not Reported
	Nortriptyline			C	Unknown	As Required		Not Reported
	Diphenhydramine Hcl			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Doxycyclin [Doxycycline]			C				Not Reported
	Restasis			C				Not Reported
	Citalopram Hydrobromide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	12913694	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-053149		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Arthropathy; Bone Erosion; Condition Aggravated; Diabetes Mellitus; Drug	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported

Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Liver Function Test Increased; Off Label Use; Peripheral Swelling; Platelet Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Crestor	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Rosuvastatin Calcium	S	Oral	0.5 Milligram, Bid	Not Reported
	Rosuvastatin Calcium	S	Oral	5.0 Milligram, Bid	Not Reported
	Imuran [Azathioprine]	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Rosuvastatin	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown		Not Reported
	Rosuvastatin	S	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Cephalexin [Cefalexin]	C	Unknown	500 Milligram, Qid	Not Reported
	Coversyl [Perindopril Erbumine]	C	Unknown	Unk	Not Reported

Prednisone	C	Unknown	10 Milligram, Qd		Not Reported
Allopurinol	C	Unknown	200 Milligram, Qd		Not Reported
Cephalexin Monohydrate	C	Unknown			Not Reported
Leflunomide	C	Unknown			Not Reported
Hydroxychloroquine	C	Unknown			Not Reported
Methotrexate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	13015479	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865701		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	M-Eslon			C	Unknown			Not Reported
	Morphine			C				Not Reported
	Statex [Morphine Sulfate]			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	14921384	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043876		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy;	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Back Pain; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	20 Milligram, Qd	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Milligram, Bid	Not Reported
	Prednisone	S	Oral	5 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram, Bid	Not Reported
	Leflunomide	S	Unknown	10 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	14921794	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044644			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Mg, 2 Every One Week		Not Reported
	Actemra			S	Subcutaneous	162 Milligram, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Mg, 3 Times/Wk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Mg, 2 Times/Wk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Q2wk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, 2 Times/Wk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	20 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15002514	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1039822		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Maculopathy; Retinopathy; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Methotrexate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15059046	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015918		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Align			C	Unknown	Unk		Not Reported

Loperamide	C	Oral	2 Mg, Unk		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported
Pantoprazole	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Celebrex	C	Unknown	Unk		Not Reported
Bifidobacterium Bifidum	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15067535	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015876		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Loperamide			C	Oral	2 Mg, Unk		Not Reported
	Pantoprazole			C	Unknown	Unk, Tid		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Align			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15665414	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2570644-00		78 YR	Female	CAN

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

Abdominal Discomfort;	Humira 40mg/0.8ml	S	Subcutaneous	Not Reported
Abdominal Discomfort;	Humira 40mg/0.8ml	S		Not Reported
Abdominal Pain Upper;	Humira 40mg/0.8ml	S		Not Reported
Abdominal Pain Upper;	Humira 40mg/0.8ml	S		Not Reported
Abdominal Pain Upper;	Arava	S	Oral	Not Reported
Abnormal Loss Of Weight;	Arava	S		Not Reported
Abnormal Loss Of Weight;	Arava	S		Not Reported
Adverse Drug Reaction;	Arava	S		Not Reported
Adverse Reaction;	Diclofenac Potassium	S	Unknown	Not Reported
Arthropathy; Arthropathy;	Enbrel	S	Subcutaneous	Not Reported
Deafness; Deafness;	Enbrel	S		Not Reported
Deafness Transitory;	Enbrel	S		Not Reported
Deafness Transitory;	Enbrel	S		Not Reported
Decreased Appetite;	Methotrexate	S	Unknown	Not Reported
Decreased Appetite;	Methotrexate	S		Not Reported
Decreased Appetite;	Methotrexate	S		Not Reported
Dizziness; Dizziness; Drug	Motrin	S	Unknown	Not Reported
Hypersensitivity; Drug	Motrin	S		Not Reported
Hypersensitivity; Drug	Motrin	S		Not Reported
Hypersensitivity; Ear	Naprosyn	S	Unknown	Not Reported
Infection; Ear Infection;	Naprosyn	S		Not Reported
Ear Infection; Eating	Naprosyn	S		Not Reported
Disorder; Feeding	Naprosyn	S		Not Reported
Disorder; Feeding	Plaquenil	S	Oral	Not Reported
Disorder; Feeding	Sodium Aurothiomalate	S	Intramuscular	Not Reported
Disorder; Foot Operation;	Sodium Aurothiomalate	S	Oral	Not Reported
Foot Operation; Functional	Voltaren	S	Unknown	Not Reported
Gastrointestinal Disorder;	Gold Sodium Thiomalate	S	Unknown	Not Reported
Functional Gastrointestinal	Gold Sodium Thiomalate	S		Not Reported
Disorder; Functional	Gold Sodium Thiomalate	S		Not Reported
Gastrointestinal Disorder;	Gold Sodium Thiomalate	S		Not Reported
Gastrointestinal Disorder;	Aspirin	S	Oral	Not Reported
Gastrointestinal Disorder;	Aspirin	S		Not Reported
Gastrointestinal Pain;	Aspirin	S		Not Reported
Gastrointestinal Pain;				
Gastrointestinal Pain;				
Headache; Headache;				
Headache; Hypophagia;				
Hypophagia;				
Musculoskeletal Disorder;				
Musculoskeletal Disorder;				
Musculoskeletal Disorder;				

Nausea; Nausea; Nausea; Off Label Use; Pharyngitis; Pharyngitis; Pharyngitis; Shoulder Arthroplasty; Shoulder Arthroplasty; Vomiting; Vomiting; Vomiting; Weight Decreased; Weight Decreased	Aspirin	S		Not Reported
	Naproxen	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac	S		Not Reported
	Diclofenac	S		Not Reported
	Diclofenac	S		Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine	S		Not Reported
	Ascorbic Acid	S	Unknown	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
	Trimethoprim	S	Unknown	Not Reported
	Acetylsalicylic Acid	S	Unknown	Not Reported
	Apo Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Clopidogrel	S	Unknown	Not Reported
	Apo Asa	S	Unknown	Not Reported
	Apo Diclofenac Ophthalmic	S	Topical	Not Reported
	Vitamin C	S	Unknown	Not Reported
	Ibuprofen	S	Unknown	Not Reported
	Acetylsalicylic Acid W/Clopidogrel	S	Unknown	Not Reported
	Apo-Diclofenac	S	Topical	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Tramadol Hydrochloride	C	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15675837	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573839-00		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety Disorder; Confusional State; Hepatic Steatosis; Infection; Knee Operation; Memory Impairment; Nausea; Nightmare; Pain; Polymyalgia Rheumatica; Rheumatoid Arthritis; Visual Impairment; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Macrobid			C				Not Reported
	Tylenol			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15767354	EXPEDITED (15-DAY)		OT	PHHY2018FR192776		30 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis; Maternal Exposure During Pregnancy; Premature Baby; Premature Delivery; Premature Rupture Of Membranes	Ursodeoxycholic Acid			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	150 Milligram Daily		Not Reported
	Azathioprine			S	Unknown	2.2 Mg/Kg, Unk		Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Unknown	5 Milligram Daily		Novartis
	Prednisone			S				Novartis
	Hydroxychloroquine			S	Unknown	150 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15855795	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2634312-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

Arava	S	Oral		Not Reported
Arava	S	Oral	For 3 Months	Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Methotrexate Sodium	S	Intramuscular		Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Plaquenil	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15935428	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2657038-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Humira			S	Subcutaneous			Not Reported

Administered; Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Cimzia	C	Subcutaneous		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	15977831	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-072428		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Osteoporotic Fracture; Spinal Compression Fracture	Orencia			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Mg, Qwk		Not Reported
	Simponi			S	Unknown	50 Mg, Q4wk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Azathioprine	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Hydroxychloroquine	C	Unknown	Unk		Not Reported
Tylenol Arthritis	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Xeljanz	C	Unknown	10 Mg, Bid		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16120764	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044085			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Q2wk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Milligram, Bid		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram		Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Mg, Qd		Not Reported
	Tiaprofenic Acid			C	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine Sulphate			C	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			C	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			C	Subcutaneous	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16226842	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110423		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abnormal Loss Of Weight; Alopecia; Arthritis; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Hepatic Enzyme Abnormal; Myocardial Infarction; Rash	Hydroxychloroquine Sulfate			S	Oral	2 Df, Qd		Sanofi
	Leflunomide			S	Oral	1 Df, Qd		Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
	Ramipril			C				Not Reported
	Rosuvastatin			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Clopidogrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16232199	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110436		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Cervical Vertebral Fracture; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Interaction; Drug Intolerance; Grip Strength Decreased; Hypophagia; Influenza; Joint Range Of Motion Decreased; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nausea; Rheumatoid Arthritis; Upper Limb Fracture; Vomiting	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Arava			S				Sanofi
	Simponi			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16232647	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110439			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			C	Unknown			Not Reported
	Methotrexate			C	Unknown	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16388804	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-050997		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Treatment Failure; Visual Impairment	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	20.0 Milligram, Qd		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400.0 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported

	Methotrexate	S	Unknown	25 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate	C	Subcutaneous	15.0 Milligram, Qwk	Not Reported
	Methotrexate	C	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Sulfasalazine	C	Oral	1.0 Gram, Qd	Not Reported
	Xeljanz	C	Oral	5.0 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16842729	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3543		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
Abnormal; Alanine Aminotransferase	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Increased; Arthralgia;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Arthropathy; Aspartate Aminotransferase	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Increased; Basal Cell Carcinoma; Blood	Methotrexate (Trade Name Unknown)			S				Not Reported
Creatinine Increased; Blood Parathyroid	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Hormone Decreased; Blood Pressure Systolic	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Increased; C-Reactive Protein Abnormal;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Contraindicated Product Administered; Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Appetite; Diarrhoea; Drug Eruption; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Intolerance; Enthesopathy; Erythema; Fatigue; Fear	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Of Injection; General Physical Health								

Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Overdose; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Methotrexate (Trade Name Unknown)	S	Subcutaneous		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Etanercept	S	Unknown		Not Reported
	Etanercept	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab Hospira	S	Intravenous (not otherwise specified)		Not Reported
	Ibuprofen	S	Oral	Every 3-4 Hours Regularly	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	2 Times/Wk	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Apo Ibuprofen	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Cyclosporine	S	Oral		Not Reported
	Apo-Cyclosporine	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Abatacept	S	Unknown		Not Reported
	Stelara	S	Subcutaneous		Not Reported

Stelara	S	Unknown		Not Reported
Golimumab	S	Subcutaneous		Not Reported
Ustekinumab	S	Subcutaneous		Not Reported
Ustekinumab	S	Unknown		Not Reported
Certolizumab Pegol	S	Subcutaneous		Not Reported
Certolizumab Pegol	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Apremilast	S	Oral		Not Reported
Apremilast	S	Unknown		Not Reported
Apremilast	S	Unknown		Not Reported
Cyclosporine	S	Oral		Not Reported
Cyclosporine	S	Unknown		Not Reported
Otezla	S	Oral		Not Reported
Otezla	S			Not Reported
Otezla	S			Not Reported
Ciclosporin	S	Oral		Not Reported
Ciclosporin	S	Unknown		Not Reported
Ciclosporin	S	Unknown		Not Reported
Sulfamethoxazole	S	Oral		Not Reported
Motrin	S	Oral	Every 3-4 Hours Regularly	Not Reported
Motrin	S	Oral		Not Reported
Motrin	S	Oral		Not Reported
Motrin	S	Unknown		Not Reported
Motrin	S	Oral		Not Reported
Motrin	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported

Orencia	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Alendronate Sodium	S	Unknown	4 Every 1 Week	Not Reported
Codeine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Arava	S	Unknown	Frequency: 1 Every 2 Day	Not Reported
Arava	S	Unknown	Frequency: 1 Every 2 Day	Not Reported
Celebrex	S	Oral		Not Reported
Cosentyx	S	Unknown		Not Reported
Cosentyx	S	Subcutaneous		Not Reported
Rituximab	S	Unknown		Not Reported
Acetaminophen	S	Unknown		Not Reported
Diphenhydramine	S	Unknown		Not Reported
Anolamine Hydrochloride [Phenylpropanolamine Hydrochloride]	S	Unknown		Not Reported
Oxycodone	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported
Mogadon	C	Unknown		Not Reported
Uloric	C			Not Reported
Colchicine	C			Not Reported
Acide Folique	C	Unknown		Not Reported

Folic Acid	C	Unknown	Not Reported
Nitrazepam	C	Unknown	Not Reported
Benadryl	C	Unknown	Not Reported
Dexilant	C	Unknown	Not Reported
Gravol	C	Unknown	Not Reported
Febuxostat	C	Unknown	Not Reported
Oxycodone Hydrochloride	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported
Cannabis Sativa	C	Unknown	Not Reported
Actonel	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported
Risedronate Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	16904609	EXPEDITED (15-DAY)		OT	GB-ADVANZ PHARMA-MAPI_00011608			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthropathy; Iron Deficiency; Lethargy; Myelodysplastic Syndrome; Pancytopenia; Platelet Count Decreased	Hydroxychloroquine			S	Unknown	200 Mg		Concordia
	Metformin Hydrochloride			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17424304	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-5764		82 YR	Female	CAN

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

Asthenia; Blood Creatinine Increased; Bone Pain; Decreased Appetite; Drug Ineffective; Dyspnoea; Feeling Hot; Heart Rate Decreased; Loss Of Personal Independence In Daily Activities; Macular Degeneration	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Shingrix	S	Unknown	Not Reported
	Nitro	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17425150	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202002000774			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Cell Death; Cholestasis; Dyspnoea; Eosinophil Count Increased; Epidermal Necrosis; Pustular Psoriasis; Pyrexia; Rash; Rash Pustular; Skin Exfoliation; Toxic Skin Eruption	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia
	Levothyrox			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17460784	EXPEDITED (15-DAY)		OT	CA-ROCHE-2554332			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Pain; Rash; Squamous Cell Carcinoma; Treatment	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Failure	Hydroxychloroquine		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Citalopram Hydrobromide		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555255		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461703	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1002		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

Diarrhoea; Drug Ineffective; Faeces Discoloured; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Liver Function Test Abnormal; Malaise; Meniscus Injury; Neuropathy Peripheral; Off Label Use; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Paraplegia; Poor Venous Access; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Disorder; Spinal Stenosis; Treatment Failure; Upper Respiratory Tract Infection	Enbrel	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Aclasta	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Tramacet	S	Oral	Not Reported
	Tramacet	S	Unknown	Not Reported
	Amitriptyline	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Depo-Medrol	C	Subcutaneous	Not Reported
	Depo-Medrol	C	Intramuscular	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Lorazepam	C	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Metformin	C	Unknown	Not Reported
	Metformin	C	Unknown	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Not Reported
	Methylprednisolone Acetate	C	Unknown	Not Reported
	Nortriptyline	C	Unknown	Not Reported

Nortriptyline	C	Unknown	Not Reported
Nortriptyline Hydrochloride	C	Unknown	Not Reported
Nortriptyline Hydrochloride	C	Unknown	Not Reported
Oxycocet	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Premarin	C	Unknown	Not Reported
Risedronate Sodium	C	Unknown	Not Reported
Tylenol 8 Hr Arthritis Pain	C	Unknown	Not Reported
Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461752	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1007		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461763	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gout; Pneumonia	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

	Colchicine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Januvia	S	Unknown	Not Reported
	Metformin	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461770	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1019			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Empyema; Musculoskeletal Stiffness; Musculoskeletal Stiffness	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461789	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1010			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Intolerance; Gastrointestinal Disorder; Hepatitis; Rash	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17461792	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1005			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Gastric Disorder; Gastric Haemorrhage; Pain; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462087	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557138			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462446	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551186		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Rituxan			S	Intravenous drip	3.0 Years		Not Reported
	Enbrel			S	Subcutaneous	3.0 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration- 3.0 Months, Frequency-Cyclical		Not Reported
	Methotrexate			S	Unknown	Therapy Duration-9.0 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	3.0 Months		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	2.0 Months		Not Reported
	Prednisone			S	Unknown	12.0 Months		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral	Therapy Duration-2.0 Months		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	12.0 Months		Not Reported
	Dexamethasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462501	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553927			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Therapeutic Product Effect Decreased; Therapeutic	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported

Response Decreased	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462583	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-015196		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Naproxen			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462604	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1026		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Adalimumab			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462721	EXPEDITED (15-DAY)		CA, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-000636			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ebstein'S Anomaly; Foetal Exposure During Pregnancy	Hydroxychloroquine			S	Transplacental	400 Milligram, Qd		Ipca
	Warfarin			S	Transplacental	Unk		Ipca
	Belimumab			S	Transplacental	10 Microgram/Kilogram		Not Reported
	Heparin			S	Transplacental	Unk		Not Reported
	Enoxaparin			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	2.5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462766	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189781			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17462854	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3293340-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Malaise; Multiple Sclerosis; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cannabis Sativa			C				Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17463135	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1020524		46 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Prednisone			S		1 Df, Qd		Not Reported
	Aspegic /00002701/			S		Unk		Mylan
	Pentoxifylline			S		1 Df, Qd		Mylan
	Kardegic			S		Unk		Mylan
	Plaquenil /00072603/			S		1 Df, Qd		Mylan
	Lovenox			S		Unk		Mylan
	Gestarelle G			S		Unk		Mylan
	Doliprane			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17463410	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189863		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Cough; Disease	Prednisone			S	Unknown			Actavis

Progression; Drug Ineffective; Immobile; Malaise	Methotrexate		S	Unknown		Barr
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram Daily;	Not Reported
	Celebrex		S	Unknown		Not Reported
	Arava		S	Unknown	20 Milligram Daily;	Not Reported
	Sulfasalazine		S	Oral	2 Gram Daily;	Not Reported
	Naproxen Sodium		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17463951	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553949		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17464142	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553858			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Zostavax	S	Intravenous (not otherwise specified)	Not Reported
Cortisone Acetate	C	Subcutaneous	Not Reported
Desoximetasone	C	Oral	Not Reported
Diclofenac	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17464189	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189738			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Topical			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Topicort[Desoximetasone]	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17464240	EXPEDITED (15-DAY)		HO	CA-ROCHE-2553935			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			C				Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17464539	EXPEDITED (15-DAY)		OT	NVSC2020CA045634			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hyperhidrosis; Inappropriate Schedule Of Product Administration;	Estradot			S	Transdermal	1 Df, Qw		Novartis
	Leflunomide			S	Unknown	20 Mg, Q24h		Not Reported

Nausea; Rheumatoid Arthritis	Methotrexate	S	Subcutaneous	25 Mg, Qw	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	2 Df, Qd	Not Reported
	Methotrexate	S	Oral	20 Mg, Qw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17464549	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020085116			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S		25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Actemra			S		Unk		Not Reported
	Apo-Leflunomide			S		20 Mg, 1x/Day		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, 2x/Day		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Wellbutrin			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17464712	NON-EXPEDITED		OT	NVSC2020US051130		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Liver Injury; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Novartis

	Prednisone		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17465228	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189663		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oedema Peripheral; Pain	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17465230	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Oral			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17465393	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3293377-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hepatic Enzyme Increased; Pyrexia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17483085	DIRECT	Y	OT			45 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
No Adverse Event	Hydroxychloroquine			S	Oral		1 MTH	Dr Reddys

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	13359948	EXPEDITED (15-DAY)		OT	CA-SA-2017SA042969			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava			S	Oral	Unk Unk, Qw		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk,Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Pregabalin			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	640 Mg, Qw		Not Reported
	Apo-Cyclosporine			S	Unknown	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg,Qw		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw		Not Reported
	Apo-Azathioprine			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Certolizumab			S	Subcutaneous	200 Mg, Qw		Not Reported
	Gold			S	Unknown	Unk Unk, Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Mg, Qw		Not Reported
	Methotrexate Sodium			S	Unknown	Unk Unk, Unk		Not Reported
	Rituximab			S	Unknown	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Simponi			S	Unknown	Unk Unk, Unk		Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	15630828	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105531		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Endocervical			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Dorzolamide Hcl Timolol Maleate			C	Unknown	2 Df, Qd		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qd		Not Reported
	Estradiol			C	Unknown			Not Reported
	Estrogel			C	Unknown	1 Df= 0.6 Percent 3 Times, Qd		Not Reported
	Furosemide			C	Unknown	40 Mg, Qd		Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Mg, Qd		Not Reported
	Valsartan			C	Unknown	320 Mg, Qd		Not Reported
	Xalatan			C	Unknown	50 Mg, Qd		Not Reported
	Zingiber Officinale			C	Unknown	500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	15856062	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633852-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	15930670	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655655-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Arthropathy; Blood Cholesterol Increased; Contraindicated Product Administered; Gastric Disorder; Granuloma; Pain In Extremity; Pruritus; Pulmonary Fibrosis; Red	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

Blood Cell Sedimentation Rate Increased; Skin Wrinkling; Spinal Osteoarthritis; Therapeutic Product Effect Decreased; Thyroid Disorder	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	16231133	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110410			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Ineffective; Juvenile Idiopathic Arthritis; Polyarthritis	Hydroxychloroquine Sulfate			S		Unk Unk, Unk		Sanofi
	Chloroquine (Salt Not Specified)			S	Oral	400 Mg, Qd		Sanofi
	Methotrexate			S		25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Prednisone			C	Oral	7 Mg, Qd		Not Reported
	Etanercept			C		50 Mg, Qw		Not Reported
	Cosentyx			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17041158	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201812-004125			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Impairment; Spinal Compression Fracture; Visual Field Defect	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Prednisolone			S	Oral	8 Mg, Qd		Not Reported
	Prednisolone			S	Oral	7 Mg, Qd		Not Reported
	Prednisolone			S	Oral	6 Mg, Qd		Not Reported
	Prednisolone			S	Oral	5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	9 Mg, Qd		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported

	Prednisolone	S	Oral	12.5 Mg, Qd	Not Reported
	Prednisolone	S	Oral	15 Mg, Qd	Not Reported
	Prednisolone	S	Oral	5 Mg, Qd	Not Reported
	Prednisolone	S	Oral	6 Mg, Qd	Not Reported
	Prograf	S	Oral	2 Mg, Qd	Not Reported
	Ulcerlmin	C		Unk	Not Reported
	Bonoteo	C		50 Mg, Q4w	Not Reported
	Diovan	C		Unk	Not Reported
	Takepron	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465134	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555249			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Rituximab			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465184	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557142			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility	Rituxan			S	Intravenous (not			Not Reported

Decreased; Osteomyelitis; Rheumatoid Arthritis			otherwise specified)	
	Apo-Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Hydrocortisone Valerate	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Lyderm [Fluocinonide]	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Sodium Aurothiomalate	C	Unknown	Not Reported
	Sodium Aurothiomalate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465267	EXPEDITED (15-DAY)		OT	IT-ROCHE-2556901		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pyrexia; Systemic Lupus Erythematosus	Mycophenolate Mofetil			S	Unknown	Unk Unk, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk Unk (7.5 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk (50 Mg Qd, Tapering Dose)		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk Unk (15 Mg Qd, Dose Tapering)		Not Reported

	Prednisone	S	Unknown	Unk (25 Mg Qd, Dose Tapering)	Not Reported
	Prednisone	S	Unknown	Unk Unk (10 Mg Qd, Dose Tapering)	Not Reported
	Prednisone	S	Unknown	Unk Unk (12.5 Mg Qd, Dose Tapering)	Not Reported
	Tacrolimus	S	Unknown	Unk Unk, Qd	Not Reported
	Methylprednisolone	C	Unknown	Unk (Pulses)	Not Reported
	Rituximab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465310	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020085748		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465380	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000971			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder;	Hydroxychloroquine			S	Unknown			Concordia

Menorrhagia; Surgery; Uterine Haemorrhage	Humira		S	Subcutaneous	Unk	Not Reported
	Humira		S			Not Reported
	Humira		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465478	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557866			Female	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465479	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557916		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465556	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557855			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective; Infection; Insomnia; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465564	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-025776		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Increased; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Hydroxychloroquine	S	Unknown			Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate	S	Unknown	22.5 Milligram		Not Reported
	Methotrexate	S	Oral	25 Milligram, Qd		Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Bid		Not Reported
	Prednisone	C	Oral	5 Milligram		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465574	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557140		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465647	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3293370-00			Male	CAN

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

C-Reactive Protein Increased; Colitis Ulcerative; Contraindicated Product Administered; Drug Ineffective; Effusion; Rheumatoid Factor Positive; Synovitis	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465649	EXPEDITED (15-DAY)		OT	CA-ROCHE-2554327			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Subcutaneous			Not Reported
	Diclofenac			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465691	EXPEDITED (15-DAY)		HO	CA-ROCHE-2557122			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Indomethacin [Indometacin]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465831	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1040		48 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Pain; Pain In Extremity; Pancreatic Carcinoma; Peripheral Swelling; Rheumatoid Arthritis; Splenectomy; Swelling; Therapeutic Product Effect	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Decreased	Plaquenil	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465832	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1013			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Plaquenil S			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Asa Ec			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17465840	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189900			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Reactine [Cetirizine]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466009	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189885			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Reactine (Cetirizine)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466010	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189902			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported

	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466020	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1189746		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Asthenia; Astigmatism; Balance Disorder; Blood Glucose Increased; Cataract; Dizziness; Fall; Fatigue; Feeling Hot; Gastric Disorder; Gastrointestinal Disorder; Head Discomfort; Headache; Hot Flush; Hypersomnia; Hypnotherapy; Incorrect Dose Administered; Insomnia; Irritable Bowel Syndrome; Kidney Infection; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Pain; Nasal Congestion; Nausea; Neck Pain; Nephrolithiasis; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pruritus; Raynaud'S Phenomenon; Sepsis; Sinusitis; Sleep Apnoea Syndrome; Stress; Therapeutic Product Effect Decreased;	Prednisone Acetate			S	Unknown			Actavis
	Prednisone Acetate			S	Unknown			Actavis
	Prednisone Acetate			S	Unknown			Actavis
	Fentanyl			S	Unknown			Cephalon
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil Hydrochloride			S	Unknown			Teva
	Belimumab			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gravol			C				Not Reported
	Neurontin			C	Unknown			Not Reported
	Neurontin			C				Not Reported

Toxicity To Various Agents; Upper Respiratory Tract Congestion; Urinary Tract Infection; Vision Blurred; Visual Impairment; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466037	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189912		71 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Drug Ineffective	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Tofacitinib			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466041	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189903			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Pulmonary Toxicity	Prednisone			S	Unknown	5 Mg		Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

	Xeljanz	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466207	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555847			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466449	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551554		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous	9.0 Months		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	9.0 Months		Not Reported
	Enbrel			S	Unknown	4.0 Years		Not Reported

Humira	S	Subcutaneous	4.0 Years	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	2.0 Years	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Pregabalin	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	2.0 Years	Not Reported
Simponi	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466577	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555862		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasopharyngitis; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466730	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06445			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported
	Triamcinolone Hexacetonide			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466855	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189699			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466876	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189709		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia;	Prednisone			S	Unknown			Actavis

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Prednisone	S	Unknown		Actavis
	Alendronate Sodium	S	Oral		Actavis
	Diclofenac Sodium	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Topicort	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Atasol [Paracetamol]	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17466992	EXPEDITED (15-DAY)		DS	CA-ROCHE-2557149		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467082	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2016-05191		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Hydroxychloroquine			S	Unknown	Unk Unk,Unk,Unknown		Lupin
	Prednisone			C	Unknown	Unk Unk,Unk,Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467235	NON-EXPEDITED		DE, OT	NVSC2020US047643		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Overdose; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	6 G		Novartis
	Ibuprofen			S	Unknown	200 Mg		Not Reported
	Naproxen			S	Unknown	750 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467282	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2020084507		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Musculoskeletal Disorder	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S				Pfizer
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467333	NON-EXPEDITED			US-PFIZER INC-2020086812		37 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467359	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020083924			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Intolerance; Finger Deformity; Foot Deformity; Gait Disturbance; Infection; Pancytopenia	Methotrexate Sodium			S	Oral	7.5 Mg, Once Weekly		Pfizer
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Leflunomide			S		20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467817	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00009890		13 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	Unknown		Unknown
	Cyclobenzaprine			S	Oral	Unknown		Unknown
	Esomeprazole			S	Oral	Unknown		Unknown
	Clindamycin			S	Oral	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17468132	DIRECT		OT				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapy Non-Responder	Plaquenil			S				Not Reported
	Methotrexate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17469402	EXPEDITED (15-DAY)		OT	NVSC2020DE049601		24 YR	Female	DEU

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

Drug Ineffective For Unapproved Indication; Lupus Nephritis	Mycophenolate Mofetil		S	Unknown	Unk		Novartis
	Hydroxychloroquine		S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17470523	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-2008857US			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Chest Pain; Respiratory Distress; Tachycardia; Unevaluable Event	Escitalopram Oxalate - Bp			S	Unknown	Unk		Allergan
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	12769741	EXPEDITED (15-DAY)		OT	CA-ROCHE-1833370			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Intentional Product Use Issue; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Varicella Zoster Vaccine Live	S	Unknown	Not Reported
	Cortisone	C	Oral	Not Reported
	Diclofenac	C	Oral	Not Reported
	Diclofenac	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C		Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	14775650	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018158011			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly (Qwk)		Pfizer
	Sulfasalazine			S	Unknown	1 Gram, Bid		Pfizer
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, 1x/Day (Qd)		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	14921372	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043586			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Burning	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb

Sensation; C-Reactive Protein Increased; Colitis; Diarrhoea; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nausea; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; White Blood Cell Count Decreased	Orencia	S	Unknown		Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Oral	15 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram	Not Reported
	Cosentyx	S	Unknown	150 Milligram	Not Reported
	Otezla	S	Oral	30 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	400 Milligram	Not Reported
	Sulfasalazine	C	Unknown	1 Gram, Bid	Not Reported
	Hydroxychloroquine	C	Unknown	200 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	15218809	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1004		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Creatinine Decreased; Blood Pressure Diastolic Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Intra-arterial			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported

General Physical Health Deterioration;	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Glossodynia; Hand Deformity; Heart Rate Decreased; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty;	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown		Not Reported
Hypersensitivity; Joint Swelling; Knee Arthroplasty; Live Birth; Malignant Melanoma; Maternal Exposure During Pregnancy; Monocyte Count Increased; Musculoskeletal Disorder; Musculoskeletal Stiffness; Neutrophil Count Increased; Off Label Use; Pain; Pemphigus; Pericarditis; Product Complaint; Product Use Issue; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Seborrhoeic Keratosis; Sinusitis; Swelling; Synovial Disorder; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Wound	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Unknown		Not Reported
	Fosamax	S	Subcutaneous		Not Reported
	Fosamax	S	Intracavernous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Cyclic	Not Reported
	Humira	S	Unknown		Not Reported

Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Subcutaneous	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported

Arava	S	Unknown	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Cortisone Acetate	S	Oral	Not Reported
Cortisone Acetate	S	Oral	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported

Cetirizine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Oral		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported
Desoximetasone	S	Oral		Not Reported
Desoximetasone	S	Unknown		Not Reported
Apo-Folic Acid	S	Unknown		Not Reported
Apo-Folic Acid	S	Unknown		Not Reported
Apo-Folic Acid	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Cetirizine	S	Unknown		Not Reported
Cetirizine	S	Unknown		Not Reported
Cetirizine	S	Oral		Not Reported
Cetirizine	S	Unknown		Not Reported
Cetirizine	S	Unknown	5mg/5 Ml	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Plaquenil	S	Oral		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
Alendronate Sodium	S	Oral		Not Reported
Alendronate Sodium	S	Unknown		Not Reported
Cortisone	S	Oral		Not Reported
Cortisone	S	Unknown		Not Reported
Topicort (Desoximetasone)	S	Subcutaneous		Not Reported

Topicort (Desoximetasone)	S	Unknown		Not Reported
Topicort (Desoximetasone)	S	Oral		Not Reported
Topicort (Desoximetasone)	S	Other		Not Reported
Apo-Sulfasalazine	S	Unknown		Not Reported
Golimumab	S	Unknown		Not Reported
Golimumab	S	Intravenous (not otherwise specified)		Not Reported
Golimumab	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Paracetamol	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Hydrocortisone Acetate	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Oral		Not Reported
Hydrocortisone Acetate	S	Other		Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Zyrtec	S	Unknown	5 Mg/5ml	Not Reported
Zyrtec	S	Unknown		Not Reported
Sarilumab	S	Unknown		Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported
Salazopyrin	S	Unknown		Not Reported

Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Cosentyx	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Atasol	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Ibuprofen	C	Unknown	Not Reported
Lisinopril	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Omega [Omeprazole]	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Vitamin C	C	Unknown	Not Reported
Ascorbic Acid	C	Unknown	Not Reported
Omeprazole	C	Unknown	Not Reported
Omeprazole Sodium	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Acetaminophen	C	Oral	Not Reported
Acetaminophen	C	Oral	Not Reported
Curamin	C	Unknown	Not Reported
Diphenhydramine Hcl	C	Oral	Not Reported
Leucovorine	C	Unknown	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
Vitamin C	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	15333538	NON-EXPEDITED		HO, OT	US-AMGEN-USASP2018118188		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Joint Swelling; Joint Warmth; Localised Infection	Enbrel			S	Unknown	Unk		Amgen
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	15935754	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656874-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	16079910	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05962		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

Prednisone	S	Unknown			Not Reported
Sulfasalazine	S	Oral			Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)			Not Reported
Tocilizumab	S	Unknown			Not Reported
Triamcinolone	S	Other	Unknown		Not Reported
Triamcinolone	S	Unknown	Unknown		Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unknown		Not Reported
Triamcinolone Hexacetonide	S	Other	Unknown		Not Reported
Apo-Naproxen	S	Unknown	Unknown		Not Reported
Apo-Prednisone	S	Oral			Not Reported
Apo-Prednisone	S	Oral			Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown		Not Reported
Hydroxychloroquine	S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	16539596	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-063602			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, 2 Every Day 1		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, 2 Every 1 Day		Not Reported
	Xeljanz			C	Oral	5 Milligram., 2 Every Day 1		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	16891755	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-29184			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Infliximab			S	Unknown	Unknown (Route Of Admin: Intracardiac)		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown (Solution)		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown (Powder For Solution Intravenous)		Not Reported
	Amlodipine			C	Unknown	Unknown		Not Reported
	Xeljanz			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17227197	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0002		64 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Prevnar 13			S	Intramuscular	Single Dose		Not Reported
	Depo-Medrol With Lidocaine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Enbrel	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Azathioprine Sodium	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Ketoprofen	S	Topical	Not Reported
Leucovorin Calcium	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Subcutaneous	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate Sodium	C	Unknown	Not Reported
Lederle Leucovorin	C	Unknown	Not Reported
Shingrix	C	Unknown	Not Reported
Corticosteroids	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17431251	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3275137-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17470756	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555241		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Mass Excision; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471374	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553868		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous drip			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Hydroxychloroquine	S	Oral	Not Reported
Imuran [Azathioprine]	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471381	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202002001039			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Balance Disorder; Cervical Radiculopathy; Condition Aggravated; Contusion; Cutaneous Lupus Erythematosus; Dehydration; Depressed Mood; Depression; Diarrhoea; Fatigue; Gastritis; Gastroenteritis Viral; Grip Strength Decreased; Headache; Hot Flush; Limb Discomfort; Multiple Sclerosis Relapse; Nausea; Rash; Spinal Pain; Toothache; Vision Blurred; Visual Impairment	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Aubagio			S	Oral	7 Mg, Qd		Not Reported
	Aubagio			S	Oral	14 Mg, Qd		Not Reported
	Cymbalta			C		Unk		Not Reported
	Cymbalta			C				Not Reported
	Ritalin			C		Unk		Not Reported
	Orsythia			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Vitamin D3			C		Unk		Not Reported
	Cyanocobalamin			C		Unk		Not Reported
	Trazodone			C		Unk		Not Reported
	Trazodone			C				Not Reported
	Zanaflex			C		Unk		Not Reported
	Carbamazepine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471519	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202002001042			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haemorrhoids; Rectal Haemorrhage	Hydroxychloroquine			S	Unknown	200 Mg		Concordia
	Leflunomide			S	Unknown	20 Mg		Not Reported
	Methotrexate			C		Unk		Not Reported
	Tofacitinib			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471549	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553830		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Treatment Failure	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471598	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2020-ES-1192454		25 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Toxic Epidermal Necrolysis	Hidroxicloroquina			S	Unknown			Teva
	Deflazacort			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471689	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1190410			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Codeine			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown	70 Mg, 4 Every 1 Week		Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous	15 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Unknown	12 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Unknown	12.5 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	40 Milligram Daily; 10 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	17.5 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Unknown	10 Mg, 4 Every 1 Week		Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17471818	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-014443		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Oral	50 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Levaquin			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Ophthalmic			Not Reported
	Baclofen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472124	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1045			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472131	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1057		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Meloxicam	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472177	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557127		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472233	EXPEDITED (15-DAY)		HO	CA-ROCHE-2556500		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Tacrolimus	S	Unknown	6.0 Dosage Forms		Not Reported
Tacrolimus	S	Unknown	5.0 Dosage Forms		Not Reported
Prednisone	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472274	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1190487			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Loss Of Consciousness	Ibuprofen			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Aleve			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472279	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1069			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Intolerance; Finger Deformity; Foot Deformity; Gait Disturbance; Infection; Pancytopenia	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17472285	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557159		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Thrombosis; Uterine Disorder; Weight Increased	Rituxan			S	Intravenous drip			Not Reported
	Cymbalta			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Metformin Hydrochloride			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Xarelto			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17473105	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01		30 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Mobicox			S	Unknown			Boehringer Ingelheim
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17473784	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2016M1049280		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatic Steatosis	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17476461	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020086707		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Off Label Use; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Losartan			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17479336	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2020M1022918		87 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Drug Interaction; Electrocardiogram Qt Prolonged	Sotalol			S	Oral	80 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Feb-2020	17480167	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-06411			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Weight Increased	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported

Prednisone	S	Unknown	Unknown		Not Reported
Rituximab	S	Unknown	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported
Plaquenil	S	Unknown	Unknown		Not Reported
Levothyroxine	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	13667464	EXPEDITED (15-DAY)		OT	CA-ROCHE-1950692		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Walking Aid User	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 7 Months		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 7 Months		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration: 2 Years		Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 10 Months		Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration: 2 Years		Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	15384083	EXPEDITED (15-DAY)		LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		64 YR	Female	CAN

BMS-2018-082847

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Dysphonia; Dyspnoea; Intentional Product Use Issue; Odynophagia; Off Label Use; Rheumatoid Arthritis; Stridor	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Golimumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	16064781	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05865		14 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hair Follicle Tumour Benign; Off Label Use; Product Use In Unapproved Indication	Infliximab			S	Unknown	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Etanercept			S	Unknown	Unknown		Not Reported
	Acetazolamide			S	Unknown	Unknown		Not Reported
	Acetazolamide			S				Not Reported
	Alendronic Acid			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Calcium Carbonate			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Ciclosporin			S				Not Reported
	Ciclosporin			S				Not Reported
	Ferric Hydroxide Polymaltose Complex			S	Unknown	Unknown		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
Leflunomide	S	Unknown	Unknown		Not Reported
Leflunomide	S				Not Reported
Methotrexate	S	Unknown	Unknown		Not Reported
Methotrexate	S	Unknown	Unknown		Not Reported
Enbrel	S	Subcutaneous	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Calcium	S	Unknown	Unknown		Not Reported
Alendronate Sodium	S	Unknown	Unknown		Not Reported
Alendronate	C	Unknown	Unknown		Not Reported
Alendronate	C	Unknown	Unknown		Not Reported
Calcium	C	Unknown	Unknown		Not Reported
Cyclosporin A	C	Unknown	Unknown		Not Reported
Cyclosporine	C	Unknown	Unknown		Not Reported
Hydroxychloroquine	C	Unknown	Unknown		Not Reported
Iron	C	Unknown	Unknown		Not Reported
Mtx	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	16079923	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05880			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported

Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Hydroxychloroquine	S	Oral			Not Reported
	Methotrexate	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Suspension Intra-Articular, Unknown		Not Reported
	Triamcinolone Acetonide	S	Unknown	Unknown		Not Reported
	Triamcinolone Acetonide	S				Not Reported
	Anakinra	S	Subcutaneous			Not Reported
	Actemra	S	Unknown			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous, Unknown		Not Reported
	Naproxen	S	Unknown	Unknown		Not Reported
	Prednisone	S	Oral			Not Reported
	Prednisone	S	Oral			Not Reported
	Triamcinolone	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	16082145	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06072			Unknown	CAN

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

Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Unknown	Unknown	Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown		Not Reported
	Triamcinolone Acetonide	S			Not Reported

	Triamcinolone Acetonide			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	16481525	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-16011		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer;	Infliximab			S	Oral	Unknown		Not Reported
	Alendronate Sodium			S	Unknown	Unknown		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown	Unknown		Not Reported
	Apo-Ibuprofen			S	Oral	Unknown		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown			Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution		Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Ibuprofen			S	Oral			Not Reported

Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Ibuprofen	S	Oral	Unknown	Not Reported
	Ibuprofen	S	Oral	Unknown	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Motrin	S	Oral		Not Reported
	Motrin	S	Oral	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Orencia	S	Subcutaneous	Unknown	Not Reported
	Orencia	S			Not Reported
	Otezla	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Remicade	S	Unknown	Unknown	Not Reported

Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Unknown, Solution	Not Reported
Stelara	S	Subcutaneous	Unknown, Solution	Not Reported
Sulfasalazine	S	Endocervical	Unknown	Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Benadryl	C	Unknown	Unknown	Not Reported
Colchicine	C	Oral	Unknown	Not Reported
Colchicine	C	Oral	Unknown	Not Reported
Colchicine	C	Unknown	Unknown	Not Reported
Dexilant	C	Unknown	Delayed Release Capsule	Not Reported
Dexilant	C	Unknown	Unknown	Not Reported
Dexilant	C	Oral	Unknown	Not Reported
Febuxostat	C	Unknown	Unknown	Not Reported
Folic Acid	C	Unknown	Unknown	Not Reported
Gravol	C	Unknown	Unknown	Not Reported
Mogadon	C	Oral		Not Reported
Mogadon	C	Oral		Not Reported
Nitrazepam	C	Unknown		Not Reported
Nitrazepam	C	Unknown		Not Reported
Nitrazepam	C	Oral		Not Reported

Oxycodone	C	Unknown	Unknown		Not Reported
Prednisone	C	Unknown	Unknown		Not Reported
Uloric	C	Unknown			Not Reported
Uloric	C	Unknown			Not Reported
Uloric	C	Oral	Unknown		Not Reported
Xeljanz	C	Unknown	Unknown		Not Reported
Alendronate Sodium	C	Unknown			Not Reported
Alendronate Sodium	C	Unknown			Not Reported
Ciclosporin	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17345827	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-02545		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Allopurinol			S	Unknown	Unknown		Not Reported
	Amitriptyline			S	Unknown	Unknown		Not Reported
	Amitriptyline			S	Unknown	Unknown		Not Reported
	Amitriptyline Hydrochloride/Perphenazine			S	Unknown	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Diclo			S	Unknown	Unknown, Tablet (Enteric Coated)		Not Reported
	Apo-Diclofenac			S	Topical	Unknown, Solution Topical		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported

Deformity	Arthrotec	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Celebrex	S	Unknown	Unknown	Not Reported
	Celebrex	S	Unknown	Unknown, Capsule, Hard	Not Reported
	Celecoxib	S	Unknown	Unknown	Not Reported
	Celecoxib	S			Not Reported
	Diclofenac	S	Unknown	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Lyrica	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Parenteral	Unknown	Not Reported
	Methotrexate	S	Oral	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Misoprostol	S	Unknown	Unknown	Not Reported
	Naprosyn	S	Unknown	Unknown	Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Nifedipine	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Pregabalin	S	Unknown	Unknown	Not Reported

Pregabalin	S	Unknown	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported
Winpred	S	Unknown	Unknown		Not Reported
Xeljanz	S	Oral			Not Reported
Xeljanz	S	Unknown			Not Reported
Xeljanz	S	Oral			Not Reported
Apo-Amitriptyline	S	Unknown	Unknown		Not Reported
Diclofenac Potassium	S	Unknown	Unknown		Not Reported
Tofacitinib	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477145	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559556		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477176	EXPEDITED (15-DAY)		DS	CA-ROCHE-2557988			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Indometacin	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Unknown	Not Reported
Morphine	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Gold	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477196	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557843			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477277	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557130		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477335	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557847			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Infection	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477359	EXPEDITED (15-DAY)		OT	CA-ROCHE-2557849		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	3.0 Months		Not Reported
	Enbrel			S	Subcutaneous	8.0 Years		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown	14.0 Years		Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477823	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06466			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown (Solution)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477873	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06742			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown (Solution Subcutaneous)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone Acetonide			S	Intra-articular	Unknown (Suspension Intra-Articular)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17477939	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-06751			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported
	Arava			S	Oral	Unknown		Not Reported

Arava	S				Not Reported
Azathioprine	S	Unknown	Unknown		Not Reported
Azathioprine	S				Not Reported
Ciclosporin	S	Unknown	Unknown		Not Reported
Ciclosporin	S				Not Reported
Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe, Solution Subcutaneous		Not Reported
Cimzia	S				Not Reported
Enbrel	S	Unknown			Not Reported
Enbrel	S				Not Reported
Gold	S	Unknown	Unknown		Not Reported
Gold	S				Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous		Not Reported
Humira	S				Not Reported
Hydroxychloroquine	S	Unknown	Unknown		Not Reported
Hydroxychloroquine	S				Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
Hydroxychloroquine Sulfate	S				Not Reported
Methotrexate	S	Unknown	Unknown		Not Reported
Methotrexate	S				Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported
Sulfasalazine	S				Not Reported
Tocilizumab	S	Unknown			Not Reported
Tocilizumab	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Feb-2020	17479823	EXPEDITED (15-DAY)		OT	NVSC2020AU053402		40 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Xolair			S	Unknown	Unk		Not Reported
	Ranitidine			S	Unknown	Unk		Novartis
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	13058844	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015725		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; Fracture; General Physical Health Deterioration; Hepatitis; Immobile; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Prednisone			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Oral	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Celecoxib			S	Unknown	Unk		Apotex
	Risedronate			S	Unknown	Unk		Apotex
	Risedronate			S	Oral	Unk		Apotex
	Sulfasalazine			S	Oral	500 Mg, Unk		Not Reported
	Sulfasalazine			S	Oral	50 Mg, Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actonel			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	Unk, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prolia			S	Subcutaneous	Unk		Not Reported
	Prolia			S				Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Q.Wk.	Not Reported
Prednisolone Sodium Phosphate	S	Unknown	Unk	Not Reported
Prednisolone Sodium Phosphate	S	Ophthalmic	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Cyclobenzaprine	C	Unknown	10 Mg, Unk	Not Reported
Desoximetasone	C	Unknown	5 Mg, Qd	Not Reported
Desoximetasone	C	Unknown	5 Mg, Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Prednisone Acetate	C	Unknown	5 Mg, Qd	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	15624942	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557652-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	Cyclical		Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Cyclical		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Sulfasalazine	C				Not Reported
	Wellbutrin	C	Oral	Modified-Release Tablet		Not Reported
	Xeljanz	C				Not Reported
	Bupropion	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	15674122	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573619-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Multiple Sclerosis; Nausea; Vomiting	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	16156564	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2731999-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	17223599	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015738		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Treatment Failure	Apo-Leflunomide			S	Oral	Unk		Apotex
	Apo-Hydro			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Hydrochlorothiazide			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk (Once In Every Two Moths)		Not Reported
	Humira			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Mar-2020	17480680	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06782			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Asthenia; Condition Aggravated; Disease Progression; Drug	Etanercept			S	Subcutaneous			Not Reported
	Arava			S	Unknown	Unknown		Not Reported

Ineffective; Drug Intolerance; Gastrointestinal Disorder; Impaired Work Ability; Internal Haemorrhage; Off Label Use; Respiratory Arrest; Visual Impairment	Enbrel	S	Subcutaneous		Not Reported
	Celebrex	S	Oral	Unknown	Not Reported
	Celecoxib	S	Oral	Unknown	Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S	Subcutaneous	Unknown	Not Reported
	Plaquenil	S	Oral		Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Prednisone	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	12233517	EXPEDITED (15-DAY)		OT	CA-ROCHE-1735234		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthenia; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Infection; Liver Function Test Increased; Nausea; Rash; Syncope; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3 Months		Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 16 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 8 Years		Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)		
	Simponi	S	Subcutaneous		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prevacid	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Prevacid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	13111752	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1876541			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia;	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 12 Months		Not Reported
Arthralgia; Aspartate Aminotransferase Increased; Basal Cell	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Carcinoma; Blood Parathyroid Hormone	Actemra			S	Unknown			Not Reported
Decreased; C-Reactive Protein Increased;	Actemra			S	Unknown			Not Reported
Condition Aggravated; Drug Eruption; Drug	Actemra			S	Unknown			Not Reported
Hypersensitivity; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
Intolerance; Drug Tolerance Decreased;	Actemra			S	Unknown			Not Reported
Erythema; Granuloma Skin; Hypercalcaemia;	Actemra			S	Unknown			Not Reported
Hypersensitivity; Inflammation; Infusion	Rituxan			S	Unknown			Not Reported
Related Reaction; Loss Of Personal Independence In	Codeine			S	Unknown			Not Reported
Daily Activities; Loss Of Personal Independence In	Humira			S	Subcutaneous	Cyclical		Not Reported
Daily Activities; Musculoskeletal Disorder;	Humira			S	Subcutaneous	Solution For Injection In Pre-Filled Syringe		Not Reported
Musculoskeletal Stiffness; Pain; Panniculitis;	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 9 Months	Not Reported
	Orencia	S	Unknown	Therapy Duration: 9 Months	Not Reported
	Remicade	S	Unknown	Therapy Duration: 365 Nos Powder For Intravesical Solution	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral	Film-Coated Tablet	Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Alendronic Acid	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral	7300 Days	Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Arava	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported

	Ciclosporin	C	Unknown			Not Reported
	Ciclosporin	C	Unknown			Not Reported
	Prednisone	C	Unknown			Not Reported
	Prednisone	C	Unknown	For 2 Months		Not Reported
	Prednisone	C	Unknown			Not Reported
	Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	15848950	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633442-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17009894	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2019479538			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Pulmonary Sepsis; Respiratory Failure; Septic Encephalopathy	No Subject Drug			S		No Dose Given		Not Reported
	Sulfasalazine			S	Unknown	3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer
	Sulfasalazine			S		3000 Mg, Qd		Pfizer

Sulfasalazine	S		3000 Mg, Qd	Pfizer
Sulfasalazine	S		3000 Mg, Qd	Pfizer
Sulfasalazine	S		3000 Mg, Qd	Pfizer
Sulfasalazine	S		3000 Mg, Qd	Pfizer
Sulfasalazine	S		3000 Mg, Qd	Pfizer
Sulfasalazine	S		3000 Mg, Qd	Pfizer
Sulfasalazine	S		3000 Mg, Qd	Pfizer
Sulfasalazine	S		3000mg, Qd	Pfizer
Sulfasalazine	S		3000 Mg, Qd	Pfizer
Sulfasalazine	S		3000 Mg, Qd	Pfizer
Sulfasalazine	S		3000 Mg, Qd	Pfizer
Sulfasalazine	S		3000 Mg, Qd	Pfizer
Sulfasalazine	S		3000mg, Qd	Pfizer
Sulfasalazine	S		3000 Mg, Qd	Pfizer
Sulfasalazine	S		Unk	Pfizer
Sulfasalazine	S		1000 Mg, Qd	Pfizer
Sulfasalazine	S		3000 Mg, Qd	Pfizer
Erelzi	S	Unknown	50 Mg, Qw	Not Reported
Hydroxychloroquine	S		250 Mg, Unk	Not Reported
Hydroxychloroquine	S		250 Mg, Unk	Not Reported
Leflunomide	S		Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Unk	Not Reported

	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	20 Mg, Unk	Not Reported
	Leflunomide	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481109	EXPEDITED (15-DAY)		OT	GB-TEVA-2020-GB-1193239		83 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Gastrointestinal Disorder; Headache; Nausea; Urinary Tract Infection	Prednisolone			S	Unknown	Initial Dose Not Stated		Actavis
	Prednisolone			S	Unknown	20 Milligram Daily; The Dose Was Tapered Further		Actavis
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cefradine			C	Unknown			Not Reported
	Amoxicillin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481183	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1070		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Arthralgia; Chills;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Diarrhoea; Drug Ineffective; Fatigue; Heart Rate Increased; Liver Function Test Increased; Nausea; Ovarian Cyst; Ovulation Pain; Pain; Pyrexia; Quality Of Life Decreased; Rash; Uterine Cyst; Vomiting; Wheelchair User; White Blood Cell Count Increased	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Benadryl	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Synthroid	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Cimzia	C	Unknown	Not Reported
	Cortisone	C	Unknown	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methylprednisolone	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481185	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1065		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gait Disturbance; Musculoskeletal Disorder; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481186	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1080			Female	CAN

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

Hypersensitivity; Pneumonia	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Arava		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481193	EXPEDITED (15-DAY)		OT	US-HETERO-HET2020US00241		40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Oseltamivir			S	Unknown			Hetero
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17481262	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555253		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased; Wrist Deformity	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17482343	EXPEDITED (15-DAY)		DE, HO, OT	US-DRREDDYS-USA/USA/20/0120229		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Circulatory Collapse; Dyspnoea; Hypotension; Hypoxia; Pulmonary Oedema; Toxicity To Various Agents	Ibuprofen			S	Oral			Not Reported
	Naproxen			S	Oral			Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17482346	EXPEDITED (15-DAY)		DS, OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Mobicox			S	Unknown			Boehringer Ingelheim
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17482499	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020086129			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate Sodium			S	Other	Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17483464	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1021060		25 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Warfarin			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	High Dose		Not Reported
	Rivaroxaban			S	Unknown	Unk		Mylan
	Apixaban			S	Unknown			Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17483713	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA054572			Male	CAN

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

Plaquenil	S	Unknown	Unk		Not Reported
Plaquenil	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S				Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Sulfasalazine	S				Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17483715	EXPEDITED (15-DAY)		LT	NVSC2020CA054458		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis	Ilaris			S	Subcutaneous	Unk (Single Use Vial)		Novartis
	Ilaris			S	Subcutaneous	Unk (Single Use Vial)		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk (Tablet)		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Endocervical	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk (Powder For Solution)	Not Reported
	Rituxan	S	Unknown	Unk (Solution Intravenous)	Not Reported
	Rituxan	S			Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17483909	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA054590			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell	Ilaris			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Humira			S	Subcutaneous	Unk, Solution		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Marijuana			S	Unknown	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria			otherwise specified)			
	Oxycodone	S	Unknown	10.0 Mg		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk, Solution Intramuscular		Not Reported
	Sulfasalazine	S	Oral	Unk, 2 Every 1 Days		Not Reported
	Sulfasalazine	S	Unknown	500.0 Mg		Not Reported
	Xeljanz	S	Oral	Unk, 2 Every 1 Days		Not Reported
	Lyrica	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17484426	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559700		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17484491	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559508		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17485303	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06944		86 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unknown, Solution		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17485752	EXPEDITED (15-DAY)		OT	US-EMCURE PHARMACEUTICALS LTD-2020-EPL-000218			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Lupus-Like Syndrome; Maternal Exposure During Pregnancy	Hydralazine Hydrochloride			S		10 Milligram Per Day		Heritage
	Hydralazine Hydrochloride			S		60 Milligram Per Day		Heritage
	Hydrochlorothiazide			S		Unk		Heritage
	Meloxicam			S		15 Milligram Daily		Heritage
	Meloxicam			S				Heritage
	Sulfasalazine			S		2 Gram, Bid		Heritage
	Sulfasalazine			S				Heritage
	Dicloxacillin			S		500 Milligram, Three Doses Over A 12-Hour Period		Not Reported
	Hydroxychloroquine			S		400 Milligram Per Day		Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisone			S		7.5 Milligram Daily		Not Reported
	Prednisone			S		20 Milligram Daily		Not Reported
	Naproxen			C		Daily		Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	17485880	EXPEDITED (15-DAY)		OT	CA-CANTON LABORATORIES, LLC-2081207		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fibromyalgia; Nausea; Oedema; Rheumatoid Arthritis; Synovitis; Vomiting	Naprosyn			S	Unknown			Canton Laboratories
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	11999787	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1618751		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cough; Drug Hypersensitivity; Fatigue; Fatigue; Immune System Disorder; Infusion Related Reaction; Nasopharyngitis; Oxygen Saturation Decreased; Oxygen Saturation Decreased; Pneumonia; Pneumonia Fungal; Pyrexia; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Diphenhydramine Hcl			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Pregabalin			C				Not Reported
	Rosuvastatin			C				Not Reported
	Aas			C				Not Reported
	Perindopril			C	Unknown			Not Reported
	Dexilant			C				Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Actonel			C				Not Reported
	Methotrexate			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Docusate			C				Not Reported
	Hydromorphone			C				Not Reported
	Calcium			C				Not Reported
	Clonazepam			C				Not Reported

U.S. FOOD & DRUG ADMINISTRATION

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	12770684	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076867		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Bone Hypertrophy; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Intentional Product Use Issue; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Q4wk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	1 Dosage Form, Qwk		Bristol Myers Squibb
	Oxycontin			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Fentanyl			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2.5 Gram, Qd		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Actemra			S	Oral			Not Reported
	Nortriptyline Hydrochloride			S	Oral	10 Milligram, Qh		Not Reported
	Myochrysine			S	Intramuscular	50 Mg, Q3wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Gabapentin			S	Oral	100 Milligram, Bid		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Celecoxib			S	Oral			Not Reported
	Apo Celecoxib			S	Oral			Not Reported
	Xeljanz			S	Oral	5 Milligram, Qd		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

Decreased; Treatment Failure	Fentanyl Matrix	S	Unknown		Not Reported
	Nortriptyline Hydrochloride;Perphenazine	S	Oral	10 Milligram, Qd, Cyclical	Not Reported
	Gabapentin	S	Oral	100 Mg, Bid	Not Reported
	Acetaminophen W/Oxycodone	C	Unknown		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Aclasta	C	Unknown	488 Milligram, Qmo	Not Reported
	Actonel	C	Unknown	36 Mg, Qwk	Not Reported
	Ascorbic Acid	C	Unknown		Not Reported
	Biotin	C	Unknown		Not Reported
	Calcium	C	Unknown	Unk Unk, Qd	Not Reported
	D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
	Diphenoxylate Hydrochloride And Atropine Sulfate	C	Unknown		Not Reported
	Diphenoxylate Hcl	C	Unknown	2.5 Milligram, Qd	Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200 Milligram, Bid	Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	Unk, Qd	Not Reported
	Epa Dha 720	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	400 International Unit, Qd	Not Reported
	Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
	Esomeprazole	C	Unknown	400 Milligram, Bid	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, 2 Every 1 Day	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	40 International Unit, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ferrous Fumarate	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
	Fish Oil	C	Unknown	1200 Milligram, Bid	Not Reported
	Folic Acid	C	Unknown		Not Reported

Genteal [Hypromellose]	C	Ophthalmic	Unk	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown		Not Reported
Loperamide	C	Unknown	2.5 Milligram	Not Reported
Nasonex	C	Unknown	2 Dosage Form, Bid	Not Reported
Nexium [Esomeprazole Magnesium]	C	Unknown	40 Mg, Bid	Not Reported
Vitamin B3	C	Unknown		Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
Oxycodone And Acetaminophen	C	Unknown		Not Reported
Oxycodone Terephthalate	C	Unknown		Not Reported
Pantoprazole	C	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole	C	Unknown	400 Milligram, Qd	Not Reported
Perfenazine	C	Oral	10 Milligram	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Prednisone	C	Unknown	5 Milligram, Q2h	Not Reported
Pyridoxine	C	Unknown		Not Reported
Retinol Palmitate	C	Unknown		Not Reported
Riboflavin	C	Unknown		Not Reported
Thiamine Hcl	C	Unknown		Not Reported
Thiamine Mononitrate	C	Unknown		Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Cyclical	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Qh	Not Reported
Sodium	C	Unknown		Not Reported
Sodium Ascorbate	C	Unknown		Not Reported
Tylenol	C	Oral	1000 Mg, Qd	Not Reported
Vitamin D3	C	Unknown		Not Reported
Vitamin A [Retinol]	C	Unknown		Not Reported
Vitamin B12 [Cyanocobalamin]	C	Unknown		Not Reported
Vitamin D [Ergocalciferol]	C	Unknown	400 Dosage Form, Qd	Not Reported

Xeljanz	C	Oral	5 Milligram, Qd	Not Reported
Fergon	C	Unknown	300 Milligram, Qd	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, Qwk	Not Reported
Multivitamin [Ascorbic Acid;Biotin;Calcium Pantothenate;Cyanocobalamin	C	Unknown		Not Reported
Omega 3 2100	C	Unknown	1200 Milligram, Bid	Not Reported
Percocet [Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol]	C	Unknown	1 Dosage Form, As Required	Not Reported
Pyridoxine Hydrochloride	C	Unknown		Not Reported
Tecta	C	Unknown	40 Milligram, Qd	Not Reported
Vitamin B1 [Thiamine]	C	Unknown		Not Reported
Vitamin C [Ascorbic Acid]	C	Unknown		Not Reported
Acetaminophen	C	Oral	1000 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	13903125	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP016854		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Apo-Hydroxyquine			S	Oral	400 Mg, Qd		Apotex
	Ramipril			S	Unknown	1 Df, Qd		Apotex
	Ramipril			S	Unknown	Unk Every One Day		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	7 Mg, Qd		Not Reported
	Prednisone			S	Unknown	7 Mg, Unk Every One Day		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Acetaminophen			S	Unknown	Unk		Apotex
	Dorzolamide ,Timolol			S	Ophthalmic	Unk		Apotex
	Dorzolamide ,Timolol			S	Unknown	Unk, Bid		Apotex

Dorzolamide ,Timolol	S	Ophthalmic	Unk, Bid	Apotex
Dorzolamide ,Timolol	S	Ophthalmic	Unk	Apotex
Dorzolamide ,Timolol	S	Ophthalmic	2 Df, Qd	Apotex
Actemra	S	Unknown	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	600 Mg, 1 Every 4 Weeks	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Levothyroxine	S	Unknown	Unk Unk, Qd	Not Reported
Levothyroxine	S	Unknown	Unk Every One Day	Not Reported
Levothyroxine	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Cosopt	S	Unknown	Unk, Bid	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk, Qd	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Tylenol /00020001/	S	Unknown	Unk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Acetaminophen With Codeine	C	Unknown	Unk As Required	Not Reported
Acetaminophen, Caffeine And Dihydrocodeine Bi	C	Unknown		Not Reported
Dorzolamide Hydrochloride W/Timolol Maleate	C	Ophthalmic	Unk, Bid	Not Reported
Plaquenil /00072602/	C	Unknown	400 Mg, Qd	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Methylprednisolone	C	Unknown	Unk	Not Reported

	Methotrexate	C	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminophen W/Caffeine	C	Unknown	Unk	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Caffeine	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Phosphate	C	Unknown	Unk	Not Reported
	Tylenol With Codein /00116401/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	14747260	EXPEDITED (15-DAY)		OT	CA-ROCHE-2105393		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Sciatica; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Caffeine;Codeine;Paracetamol			S	Unknown			Not Reported
	Tylenol No.2			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported

	Cosopt	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Codeine Phosphate	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Diphenhydramine	C			Not Reported
	Methylprednisolone	C			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown		Not Reported
	Tylenol	C			Not Reported
	Acetaminophen	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	15855790	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633737-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	16719246	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2892951-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Drug Ineffective; Infection; Liver Function Test Increased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Seizure; Therapeutic Product Effect Decreased; Thyroid Disorder	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17222231	EXPEDITED (15-DAY)		OT	GR-MYLANLABS-2019M1131972		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Metformin			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Mylan
	Exemestane			S	Unknown	Unk		Mylan
	Exemestane			S		Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Ramipril			S	Unknown	Unk		Mylan
	Ramipril			S	Unknown	Unk		Mylan
	Levothyroxine Sodium			S	Unknown	Unk		Mylan
	Lansoprazole			S	Unknown	Unk		Mylan
	Lansoprazole			S	Unknown	Unk		Mylan
	Belimumab			S	Unknown	Unk		Mylan

	Belimumab	S	Unknown	Unk	Mylan
	Belimumab	S	Unknown	Unk	Mylan
	Belimumab	S	Unknown	Unk	Mylan
	Belimumab	S	Unknown	Unk	Mylan
	Belimumab	S	Unknown	Unk	Mylan
	Azathioprine	S	Unknown	Unk	Mylan
	Azathioprine	S	Unknown	Unk	Mylan
	Prednisolone	S	Unknown	Unk	Mylan
	Prednisolone	S	Unknown	Unk	Mylan
	Thyroxine	S	Unknown	Unk	Mylan
	Thyroxine	S	Oral	Unk	Mylan
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Mylan
	Dicumarol	C	Unknown	Unk	Mylan
	Dicumarol	C	Unknown	Unk	Mylan
	Dicumarol	C	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17226111	EXPEDITED (15-DAY)		OT	CA-INTERCEPT-PMOCA2018001237		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Alkaline Phosphatase Abnormal; Decreased Appetite; Fatigue; Gamma-Glutamyltransferase Increased; Malaise; Nausea; Therapy Cessation; Weight Decreased; White Blood Cell Count Decreased	Ocaliva			S	Oral	5 Mg, Qd		Intercept Pharmaceuticals
	Ursodiol			S		750 Mg, Qd		Not Reported
	Ursodiol			S		750 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17466040	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555235			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn [Naproxen]			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Leflunomide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17485751	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202002001128			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17485790	EXPEDITED (15-DAY)		OT	AU-ROCHE-2560432		40 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective	Xolair			S	Unknown	Unk		Not Reported
	Ranitidine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486058	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	Dosage Form: Not Specified		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Form: Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Form: Solution.		Not Reported
	Depo-Medrol			C	Other	Form: Suspension Intraarticular		Not Reported
	Depo-Medrol			C	Other			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown	Tablet (Entericcoated)		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown			Not Reported

Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486321	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201710-006133			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Incorrect Route Of Product Administration; Infection; Pneumonia; Synovitis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk, Tablet		Concordia
	Arava			S	Oral	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk, Weekly		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Freq: Unk X 1 Weeks		Not Reported
	Methotrexate			S	Intra-articular	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486336	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201801-000172			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Loss Of Personal Independence In Daily Activities; Nausea;	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk Unk, Bid		Concordia

Rheumatoid Arthritis	Hydroxychloroquine	S	Oral	200 Mg, Bid	Concordia
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	25 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	25 Mg, Monthly (Q4w)	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Sulfasalazine	S	Oral	1 G	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S		25 Mg, Weekly	Not Reported
	Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486424	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1191653			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Etanercept			S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486441	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2558002			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction;	Rituxan			S	Intravenous (not			Not Reported

Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Wheelchair User				otherwise specified)	
	Sulfasalazine		S	Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine		S	Oral	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Arava		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486453	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1191742			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infection; Pneumonia	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Intra-arterial			Barr
	Naproxen Sodium			S	Unknown			Teva
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486497	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1191724			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486522	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560384		74 YR	Female	CAN

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

Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Apo-Azathioprine	S	Oral		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Kineret	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486594	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1128		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Off Label Use; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Losartan	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17486971	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-238900		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disease Progression; Pseudomonas Infection; Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Hydroxychloroquine			S	Unknown			Sun
	Prednisolone			S	Unknown	60 Milligram		Taro
	Prednisolone			S				Taro
	Mycophenolate			S	Unknown			Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17487663	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020089097			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Dysphagia; Gastrointestinal Disorder; Hepatitis; Muscle Disorder; Skin Disorder	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 1x/Day		Not Reported
	Mycophenolate			S		1 G, 2x/Day		Not Reported
	Myfortic			S		Unk		Not Reported
	Prednisone			S		Unk Unk, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17487715	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020092939			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Affective Disorder; Arthralgia; Depression; Drug Ineffective; Frequent Bowel Movements; Gastric Disorder; Glaucoma; Joint Swelling; Musculoskeletal Stiffness; Nausea; Psoriasis	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Pfizer
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Unk		Not Reported
	Prednisone			S	Unknown	25 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17487719	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020091248		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Sulfasalazine			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17487720	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020093003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Methotrexate Sodium			S				Pfizer
	Anakinra			S		Unk, 1x/Day		Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Orencia			S				Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17487793	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020091022			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Nausea; Treatment Failure	Methotrexate Sodium			S	Oral	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Mar-2020	17495298	EXPEDITED (15-DAY)		DE, OT	US-FRESENIUS KABI-FK202002123		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Embolic Stroke; Endocarditis; Thrombocytopenia; Whipple'S Disease	Methylprednisolone (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Celecoxib			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclobenzaprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	14746343	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009150		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass; Mass Excision; Nodule;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Subcutaneous	Unk		Not Reported
	Risedronate			S	Unknown	Unk		Apotex
	Risedronate			S	Oral	35 Mg, Q.Wk.		Apotex

Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	22.5 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Novo-Rythro	S	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	200 Mg, Bid	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	4000 Iu, Qd	Not Reported
	Marijuana	C	Unknown	Unk	Not Reported
	Risedronate	C	Oral	35 Mg, Q.Wk.	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported
	Wellbutrin	C	Unknown	300 Mg, Qd	Not Reported
	Bupropion	C	Unknown	300 Mg, Qd	Not Reported
	Cannabis Sativa	C	Unknown	Unk, Unknown	Not Reported
	Hydroxychloroquine	C	Oral	400 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	15207176	EXPEDITED (15-DAY)		OT	PHHY2018GB052187		51 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Adrenal Suppression; Blood Prolactin Increased; Cushing'S Syndrome; Drug Interaction; Galactorrhoea; Hyperprolactinaemia; Myopathy; Orthostatic Hypotension	Itraconazole			S	Oral	100 Mg, Qd		Novartis
	Itraconazole			S	Oral	100 Mg, Qd		Novartis
	Levothyroxine			S	Unknown	75 Mg, Qd		Not Reported
	Domperidone Maleate			S	Unknown	10 Mg, Tid		Not Reported
	Prednisolone Acetate			S	Unknown	7.5 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Immunoglobulin I.V			S	Unknown	Unk		Not Reported

Creon	S	Unknown	10 Mg, Tid		Not Reported
Lansoprazole	S	Unknown	30 Mg, Qd		Not Reported
Uniphyllin	S	Unknown	200 Mg, Bid		Not Reported
Carbocisteine	S	Unknown	2 Df, Qd		Not Reported
Carbocisteine	S	Unknown	750 Mg, Bid		Not Reported
Risedronate	S	Unknown	35 Mg		Not Reported
Amylase	S	Unknown	10 Mg, Tid		Not Reported
Propanolol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	15320874	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2018341914		66 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Joint Swelling; Joint Warmth; Localised Infection	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	15619748	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555750-00		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain;	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported

Peripheral Swelling; Rheumatoid Arthritis	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Orencia		S		Not Reported
	Plaquenil		S	Unknown	Not Reported
	Prednisone		S	Oral	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	15735711	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2595527-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Hospitalisation; Injury; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			C	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	15849613	EXPEDITED (15-DAY)		OT	CA-SA-2019SA012286			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S				Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Methotrexate			S		15 Mg		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Leflunomide			S		Unk Unk, Qd		Sanofi
	Leflunomide			S		10 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Humira			S		40 Mg		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S		Unk		Not Reported
	Prednisone			C				Not Reported
	Arava			C				Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	16752576	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2456918-00		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Joint Swelling;	Humira 40mg/0.8ml			S	Subcutaneous	Frequency- Cyclical		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Knee Operation; Musculoskeletal Stiffness; Off Label Use; Product Use Issue; Psoriasis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Salmeterol/Fluticason	C	Respiratory (inhalation)	250-50 Mcg	Not Reported
	Levothyroxine Sodium	C	Oral		Not Reported
	Alprazolam	C	Oral	Prn	Not Reported
	Prednisone	C			Not Reported
	Celebrex	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17395555	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007224		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Q.H.		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Unk, Cyclical		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Risedronate			S	Oral	35 Mg, Q.Wk.		Doc Generici
	Risedronate			S	Unknown	35 Mg, Q.Wk.		Doc Generici
	Risedronate			S	Unknown	35 Mg, Q.Wk.		Apotex
	Risedronate			S	Oral	35 Mg, Q.Wk.		Apotex
	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Qid		Apotex
	Hydroxychloroquine			S	Unknown	Unk Unk, Qd		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Q.H.		Apotex
	Hydroxychloroquine			S	Unknown	Unk Unk, Q.Wk.		Apotex
	Hydroxychloroquine			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk, Cyclical		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex

Hydroxychloroquine	S	Unknown	Unk	Apotex
Actemra	S	Intravenous (not otherwise specified)	8 Df, Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Subcutaneous	100 Mg, Unk	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	300 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk, Cyclical	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Oral	Unk	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17484448	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559662		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Rituximab			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Medroxyprogesterone Acetate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C				Not Reported
	Cyclosporine			C	Unknown			Not Reported
	Depo-Provera			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17490734	EXPEDITED (15-DAY)		OT	IT-LAURUS LABS LIMITED-202000070		34 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Capillary Leak Syndrome; Off Label Use	Hydroxychloroquine			S	Unknown			Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491494	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560163		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491499	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular	Suspension Intra-Articular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported

Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Plaquenil [Hydroxychloroquine Phosphate]		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491509	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Minocycline			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491534	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560160			Female	CAN

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

Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Atorvastatin	C	Unknown	Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491554	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560158		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral	Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491788	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1166			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Other			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491790	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201709-005553			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Pulmonary Toxicity; Visual Impairment	Hydroxychloroquine			S	Oral	Unk		Concordia
	Methotrexate			C		Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Orencia			C		Unk		Not Reported
	Cimzia			C		Unk		Not Reported
	Simponi			C		Unk		Not Reported
	Inflectra			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17491976	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559690		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Cimzia	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492138	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559679		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492232	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201703-001950			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity;	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Oral	Unk Unk, Weekly	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	640 Mg,	Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Weekly	Not Reported
	Enbrel	S	Unknown	50 Mg	Not Reported
	Humira	S	Subcutaneous	40 Mg, Weekly	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Weekly	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Certolizumab	S	Subcutaneous	200 Mg, Weekly	Not Reported
	Pregabalin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Weekly	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492501	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559502			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis;	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Weight Increased	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Rituximab		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Levothyroxine		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492506	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1192433			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bacterial Disease Carrier; Depressed Mood; Emotional Distress; Exostosis; Labelled Drug-Drug Interaction Medication Error; Pleural Effusion; Pleural Thickening; Pneumothorax; Rheumatoid Arthritis; Rib Fracture	Naproxen Sodium			S	Oral	500 Milligram Daily;		Teva
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492547	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202002000969			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17492862	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1192412			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Haemoglobin Decreased; Musculoskeletal Disorder; Nausea; Pain In Extremity; Peripheral Swelling; Vomiting; Weight Decreased	Naproxen Sodium			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17493033	EXPEDITED (15-DAY)		HO	CA-ROCHE-2555409		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Tocilizumab			S	Unknown			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Naproxen			C				Not Reported
	Plaquenil Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17493052	EXPEDITED (15-DAY)		DS	CA-ROCHE-2560161		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Subcutaneous	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Bupropion		C	Unknown	Not Reported
	Esomeprazole		C	Unknown	Not Reported
	Folic Acid		C	Unknown	Not Reported
	Levothyroxine		C	Unknown	Not Reported
	Naproxen		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17493140	EXPEDITED (15-DAY)		DS, OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Mobicox			S	Unknown			Boehringer Ingelheim
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17493184	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560157			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17493887	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1192504		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Celecoxib			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17494074	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2020-US-1193378		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Drug Ineffective; Overdose; Pulmonary Oedema; Toxicity To Various Agents	Hydroxychloroquine			S	Oral	6 G Missing		Not Reported
	Ibuprofen			S	Oral			Actavis
	Epinephrine			S	Unknown			Teva
	Naproxen			S	Oral			Teva
	Potassium			S	Unknown			Actavis
	Norepinephrine			S	Unknown			Teva
	Sodium Bicarbonate			S	Unknown	Drips		Not Reported

	Calcium	S	Unknown	Not Reported
	Dextrose-50	S	Unknown	Not Reported
	Vasopressin	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17494702	EXPEDITED (15-DAY)		DE, OT	IN-APPCO PHARMA LLC-2081256		41 YR	Female	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acinetobacter Infection; Brain Abscess; Death; Nocardiosis; Septic Shock; Shunt Infection	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Prednisolone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17497976	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-016630		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17498115	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1192439			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain	Celecoxib			S	Oral	400 Milligram Daily;		Teva
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17498463	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise;	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form- Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection; White Blood Cell Count Decreased			otherwise specified)			
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Depo-Medrol	C	Intra-articular	Dosage Form- Suspension Intra-Articular		Not Reported
	Diclofenac	C	Unknown			Not Reported
	Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	13950566	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-080121			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Drug Ineffective; Eye Disorder; Hepatic Enzyme Increased; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Peripheral Swelling; Pruritus; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg, Qwk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral			Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	14310480	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050909		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Ankle Fracture; Contraindicated Product Administered; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Swelling; Malaise; Nausea; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Unevaluable Event; Vomiting	Cimzia			S	Subcutaneous	Solution		Not Reported
	Actemra			S		162 Milligram		Not Reported
	Arava			S		20 Mg, Once Daily (Qd)		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		20 Milligram, Once Daily (Qd)		Not Reported
	Methotrexate			S		25 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	2 G, Once Daily (Qd)		Not Reported
	Gold			C				Not Reported
	Plaquenil			C		Unk		Not Reported
	Acetaminophen;Codeine Phosphate			C				Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine			S		400 Milligram		Not Reported
	Prednisone			C		15 Milligram, Once Daily (Qd)		Not Reported
	Pregabalin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	14956006	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2017-		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

Underdose; Product Use Issue; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Infliximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Unknown	Not Reported
	Adalimumab	S	Unknown	Unknown	Not Reported
	Adalimumab	S			Not Reported
	Abatacept	S	Intravenous drip		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous	Unknown	Not Reported
	Anakinra	S	Unknown	Unknown	Not Reported
	Apo-Hydroxyquine	S	Oral	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Naproxen	S	Oral	Tablet (Enteric Coated)	Not Reported
	Apo-Naproxen	S	Oral	Tablet (Enteric Coated)	Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Naproxen	S	Oral		Not Reported
	Apo-Naproxen	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported

Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Triamcinolone Aq	S	Unknown	Unknown	Not Reported
Apo-Triamcinolone Aq	S	Unknown	Spray Metered Dose	Not Reported
Apo-Sulfasalazine	S	Oral		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Naproxen	S			Not Reported
Orencia	S	Intravenous drip		Not Reported
Orencia	S	Unknown	Inhalation	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous drip		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported

Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Unknown	Unknown	Not Reported
Prednisone	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S			Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown	Not Reported
Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported
Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Unknown	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	Unknown	Not Reported
Humira	S	Subcutaneous	Unknown	Not Reported
Humira	S	Subcutaneous	Unknown. Solution	Not Reported
Humira	S	Unknown	Unknown	Not Reported

Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)			Not Reported
Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)			Not Reported
Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)			Not Reported
Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Kineret	S	Subcutaneous	Per Syringe Single-Use, Preservative-Free Pre-Filled Syringes, Solution Subcutaneous		Not Reported
Kineret	S				Not Reported
Triamcinolone	S	Unknown	Unknown		Not Reported
Triamcinolone	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unknown		Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unknown		Not Reported
Triamcinolone Hexacetonide	S				Not Reported
Folic Acid	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	15635243	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105931			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Back Injury; Drug Ineffective; Fall; Headache; Liver Function Test Increased; Nausea; Off Label Use; Product Label Confusion; Rheumatoid Arthritis;	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, Qd		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine			S	Oral			Not Reported

Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Phosphate]				
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Enbrel	C	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Etanercept	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	160 Milligram	Not Reported
	Cimzia	C	Subcutaneous		Not Reported
	Imuran [Azathioprine Sodium]	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	15814007	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2018375765			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Chronic Obstructive Pulmonary Disease; Haemorrhoids; Mucosal Inflammation; Rheumatoid Arthritis; Transaminases Increased; Weight Decreased	No Subject Drug			S		No Dose Given		Not Reported
	Methotrexate Sodium			S		15 Mg, Unk		Pfizer
	Methotrexate Sodium			S		15 Unk, Unk		Pfizer
	Methotrexate Sodium			S		15 Mg, Unk		Pfizer
	Methotrexate Sodium			S		15 Mg, Unk		Pfizer
	Methotrexate Sodium			S		15 Unk, Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		500 Mg, Unk		Pfizer
	Sulfasalazine			S		500 Mg, Unk		Pfizer
	Leflunomide			S		10 Mg, Unk		Not Reported
	Leflunomide			S		10 Unk, Unk		Not Reported

	Leflunomide	S	10 Mg, Unk	Not Reported
	Hydroxychloroquine	S	200 Mg, Unk	Not Reported
	Hydroxychloroquine	S	200 Mg, Unk	Not Reported
	Hydroxychloroquine	S	200 Mg, Unk	Not Reported
	Roactemra	S	162 Mg, Unk	Not Reported
	Erelzi [Etanercept]	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	16471647	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-15759		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Flushing; Interstitial Lung Disease; Off Label Use	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported

Esomeprazole	C	Unknown			Not Reported
Lumigan Rc	C	Ophthalmic	Unknown		Not Reported
Nexium	C	Unknown	Unknown		Not Reported
Suphedrine	C	Unknown			Not Reported
Trazodone	C	Unknown			Not Reported
Tylenol	C	Unknown			Not Reported
Valsartan	C	Unknown	Unknown		Not Reported
Valsartan	C	Unknown	Unknown		Not Reported
Wellbutrin Xl	C	Unknown	Extended Release		Not Reported
Wellbutrin Xl	C	Unknown			Not Reported
Esomeprazole Sodium	C	Unknown	Unknown		Not Reported
Acetaminophen	C	Unknown			Not Reported
Acetaminophen	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	16480475	EXPEDITED (15-DAY)		OT	US-MALLINCKRODT-T201804782			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Anxiety; Arthralgia; Arthritis; Back Pain; Blood Cholesterol Abnormal; Blood Sodium Increased; Blood Uric Acid Increased; Chest Pain; Depression; Dizziness; Eye Haemorrhage; Fatigue; Gait Disturbance; Headache; Heart Rate Increased; Hyperhidrosis; Hypertension; Hypoaesthesia; Immune System Disorder; Infection; Influenza; Insomnia; Malaise;	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 1 Time Weekly Sunday		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 1 Time Weekly Sunday		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 1 Time Weekly (Sunday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 Ml, 1 Time Weekly (Sunday)		Mallinckrodt
	Repository Corticotropin Injection			S	Unknown	40 Units/1 Ml		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	40 Units/0.5 Ml, 1 Time Weekly (Sunday)		Mallinckrodt
	Repository Corticotropin Injection			S	Subcutaneous	40 Units / 0.5 Ml, 1 Time Weekly, Sunday		Mallinckrodt

Memory Impairment; Menorrhagia; Mental Fatigue; Mobility Decreased; Mood Altered; Muscle Spasms; Muscular Weakness; Nausea; Nervousness; Pain; Pain In Extremity; Pallor; Papilloedema; Poisoning; Polymenorrhoea; Product Dose Omission; Proteinuria; Renal Impairment; Sciatica; Sensitivity To Weather Change; Somnolence; Stress; Systemic Lupus Erythematosus; Vision Blurred; Visual Impairment; Vomiting; Weight Decreased	Repository Corticotropin Injection		S	Subcutaneous	80 Units / 1 Ml, 1 Time Weekly, Sunday	Mallinckrodt
	Plaquenil		S	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	5 Mg, Unk	Not Reported
	Prednisone		C	Unknown	Unk, Every Other Day	Not Reported
	Prednisone		C	Unknown	Unk, Once A Day	Not Reported
	Cellcept		C	Unknown	Unk	Not Reported
	Benlysta		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17388691	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP006368		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Back Pain; Constipation; Dactylitis; Diarrhoea; Disability; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Finger Deformity; Inappropriate Schedule Of Product Administration; Inappropriate Schedule Of Product Administration; Inflammation; Injury; Insomnia; Joint Effusion; Joint Stiffness; Joint Swelling; Loss Of	Amitriptyline			S	Unknown	Unk, Unknown		Apotex
	Allopurinol			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Cymbalta			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown	Unk		Not Reported
	Allopurinol			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk, Unknown		Not Reported
	Clonazepam			C	Unknown	1 Mg, Unk		Not Reported

Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Migraine; Muscle Spasms; Nausea; Osteoarthritis; Paraesthesia; Psoriasis; Sleep Apnoea Syndrome; Synovial Cyst; Synovitis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Ergocalciferol	C	Unknown	4000 Iu, Qd	Not Reported
	Flaxseed Oil	C	Unknown	Unk	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	D-Alpha Tocopherol	C	Unknown	Unk, Unknown	Not Reported
	Linum Usitatissimum	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	7412801	EXPEDITED (15-DAY)		OT	TR-SANOFI-AVENTIS-2010SA030554		57 YR	Female	TUR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity; Visual Acuity Reduced; Visual Impairment	Hydroxychloroquine			S	Unknown	200 Mg,Qd		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17498943	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-238987		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Injury	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499155	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3300813-00		70 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Kidney Disease; Drug Ineffective; Multimorbidity; Off Label Use; Product Use Issue;	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Synovitis	Hydroxychloroquine	S	Unknown		Not Reported
	Azathioprine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499291	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201710-005903			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	Unk		Concordia
	Leflunomide			S	Oral	Unk		Not Reported
	Humira			C	Subcutaneous	Unk		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Orencia			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	50 Die		Not Reported
	Azathioprine			C		Unk		Not Reported
	Imuran			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499294	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1188			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Nausea; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499295	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499349	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560421			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499478	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201801-000125			Unknown	CAN

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

Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine	S	Unknown		Concordia
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Concordia
	Hydroxychloroquine	S	Unknown		Concordia
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Weekly, (Qow)	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Mg, Weekly (Q4w)	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Monthly, Powder And Solution For Solution For Injection	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Myocrisin	S	Unknown	Unk	Not Reported
	Arava	C		20 Mg, Qd	Not Reported
	Arava	C		Unk	Not Reported
	Ativan	C			Not Reported
	Dilaudid	C			Not Reported
	Enablex	C			Not Reported
	Lasix	C			Not Reported
	Loperamide	C			Not Reported
	Norflex	C			Not Reported
	Omnaris	C			Not Reported
	Pantoloc	C			Not Reported
	Synthroid	C			Not Reported
	Vagifem	C			Not Reported
	Abatacept	C			Not Reported
	Rituxan	C			Not Reported
	Kineret	C			Not Reported
	Benadryl Allergy	C			Not Reported
	Cortisone	C			Not Reported
	Desoximetasone	C			Not Reported
	Diphenhydramine	C			Not Reported
	Plantago Ovata	C			Not Reported
	Actemra	C			Not Reported

					Sodium Aurothiomalate	C				Not Reported
					Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17499831	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202002001191			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Haemorrhage	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Erelzi			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Leflunomide			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17500067	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2020-BI-01			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness;	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Form: Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Depo-Medrol			C	Unknown	Suspension Intra-Articular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Humira			C	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17500720	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559521		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous drip			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17500766	EXPEDITED (15-DAY)		OT	US-ZYDUS-048013		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Erythema; Macule; Pain Of Skin; Skin Plaque; Varicella Zoster	Hydroxychloroquine			S	Unknown			Zydus Pharm
	Azathioprine			S	Unknown			Zydus Pharm

Virus Infection	Prednisone		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17501274	EXPEDITED (15-DAY)		DE, LT, OT	US-STRIDES ARCOLAB LIMITED-2020SP002142		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Completed Suicide; Crying; Dyspnoea; Hypotension; Oxygen Saturation Decreased; Pulmonary Oedema; Pupil Fixed; Salivary Hypersecretion	Ibuprofen			S	Oral	Unk, (Tablets)		Strides
	Naproxen			S	Oral	Unk, (Tablets)		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17501565	NON-EXPEDITED			US-PFIZER INC-2020097824		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Arthrotec			S		Unk		Pfizer
	Azulfidine			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Phenobarbital			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17501605	NON-EXPEDITED			US-PFIZER INC-2020097853		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Arthrotec			S		Unk		Pfizer

	Azulfidine	S	Unk	Pfizer
	Phenobarbital	S	Unk	Pfizer
	Codeine	S	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17504725	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1193099		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline Hydrochloride			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2020	17504736	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1193102		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Minocycline Hydrochloride			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine Sulfate	S	Oral			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Xeljanz	S	Unknown	10 Milligram Daily;		Not Reported
Amoxicillin Sodium;Clavulanate Potassium	C	Unknown			Not Reported
Amoxil [Amoxicillin]	C	Unknown			Not Reported
Bacillus Calmetteguerin Bcg	C	Intravenous (not otherwise specified)			Not Reported
Leflunomide	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	13103523	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876554		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Mycophenolate Mofetil Hydrochloride	S	Unknown	Not Reported
	Apo Mycophenolate	S	Unknown	Not Reported
	Mycophenolate	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Leflunomide	C		Not Reported
	Morphine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	14767196	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018049244		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Musculoskeletal Stiffness	Enbrel			S	Unknown	Unk		Amgen
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	15067533	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015880			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product	Leflunomide			S	Unknown	Unk		Apotex
	Rituximab			S	Unknown	Unk		Not Reported

Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Actemra	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Bifidobacterium Bifidum	C	Unknown	Unk	Not Reported
	Loperamide	C	Oral	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk, Tid	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	15076376	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015960		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Herpes Zoster; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Etanercept			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Citalopram			C	Unknown	20 Mg, Qd		Not Reported
	Folic Acid			C	Unknown	5 Mg, Qd		Not Reported
	Losec /00661201/			C	Unknown	20 Mg, Qd		Not Reported
	Naprosyn /00256201/			C	Unknown	500 Mg, Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	16284325	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019016961		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Nausea; Off Label Use; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram, Solution		Not Reported
	Orencia			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram, Unk		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S				Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Kevzara			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S		20 Milligram		Not Reported
	Methotrexate			S		10 Milligram		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported
	Prednisone			C		10 Milligram		Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	16519993	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017276980		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Musculoskeletal Stiffness	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		1 G, 2x/Day		Pfizer
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Orencia			S		Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	16600153	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-068088		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	160 Milligram, Qwk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram, Qd		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk		Not Reported
	Plaquenil S			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	Unk		Not Reported

Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	16838640	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-27173			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomadesis; Onychomycosis	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituximab			S	Subcutaneous	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	Unknown		Not Reported
	Arava			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17142317	EXPEDITED (15-DAY)		DS, HO, OT	CA-UCBSA-2019051903		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Cimzia			S	Subcutaneous	Solution		Not Reported
	Alendronate Sodium			S		70 Milligram, 4x/Week		Not Reported
	Apo-Ibuprofen			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apremilast			S		60 Milligram, 2x/Day (Bid)		Not Reported
	Apremilast			S		Unk		Not Reported
	Apremilast			S				Not Reported
	Ciclosporin			S		Unk		Not Reported
	Ciclosporin			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram, Solution		Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Ibuprofen			S	Oral	600 Milligram		Not Reported
	Infliximab			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S		70 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			S		12 Milligram, 4x/Week		Not Reported
	Methotrexate			S		17.5 Milligram, 4x/Week		Not Reported
	Methotrexate			S		10 Milligram, 4x/Week		Not Reported
	Methotrexate			S		15 Milligram, Weekly (Qw)		Not Reported

Methotrexate	S		12.5 Milligram, 4x/Week	Not Reported
Motrin [Ibuprofen]	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
Motrin [Ibuprofen]	S	Oral	600 Milligram, Once Daily (Qd)	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S			Not Reported
Orencia	S		Unk	Not Reported
Orencia	S			Not Reported
Otezla	S		Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, 2x/Day (Bid)	Not Reported
Simponi	S	Subcutaneous	Solution	Not Reported
Stelara	S	Subcutaneous	Solution	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Tocilizumab	S		360 Milligram	Not Reported
Tocilizumab	S		680 Milligram	Not Reported
Enbrel	S		25 Milligram, 2x/Week	Not Reported
Enbrel	S		Unk	Not Reported
Enbrel	S			Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C			Not Reported
Colchicine	C		Unk	Not Reported
Dexilant	C			Not Reported
Febuxostat	C			Not Reported
Folic Acid	C			Not Reported
Gravol	C		Unk	Not Reported
Mogadon	C			Not Reported
Nitrazepam	C			Not Reported
Oxycodone	C			Not Reported
Prednisone	C		Unk	Not Reported
Uloric	C			Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17370536	EXPEDITED (15-DAY)		OT	FI-PFIZER INC-2020047226		51 YR	Female	FIN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mycobacterial Infection	Sulfasalazine			S		Unk		Pfizer
	Trexan			S		Unk		Pfizer
	Oxiklorin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17405600	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000668			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Decreased Appetite; Dyspepsia; Eczema; Nodule; Psoriatic Arthropathy; Weight Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Otezla			S	Oral	60 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17456605	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007874		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Meloxicam			S	Unknown	15 Mg, Unk		Apotex
	Humira			S	Subcutaneous	Unk		Not Reported
	Atorvastatin Calcium			C	Unknown	20 Mg, Unk		Not Reported
	Budesonide W/Formoterol Fumarate			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	100 Mg, Unk		Not Reported
	Lansoprazole			C	Unknown	30 Mg, Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported

	Plaquenil /00072602/			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17505326	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201801-000222			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective; Dysgeusia; Fluid Retention; Lower Respiratory Tract Infection; Musculoskeletal Pain; Pain In Extremity	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Folic Acid			S	Unknown	1 Mg, Qd		Not Reported
	Meloxicam			S	Unknown	15 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17505473	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1193773			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Immunoglobulin A Increased; Coeliac Disease; Discomfort; Malaise; Nausea; Pain	Hydroxychloroquine Sulfate			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17506038	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1207			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Affective Disorder; Arthralgia; Depression; Drug Ineffective; Frequent Bowel Movements; Gastric Disorder; Glaucoma; Joint Swelling; Musculoskeletal Stiffness; Nausea;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

Psoriasis	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17506284	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560155			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Amoxicillin;Clavulanate Potassium			C				Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17507539	EXPEDITED (15-DAY)		HO, LT	ES-ACCORD-175043		44 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Drug Interaction; Off Label Use	Methotrexate			S	Subcutaneous			Accord
	Dolquine			S	Oral	Strength: 200 Mg, 30 Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17508707	EXPEDITED (15-DAY)		HO, OT	IT-IPCA LABORATORIES LIMITED-IPC-2020-IT-000811			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Capillary Leak Syndrome	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17509582	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563624		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17509657	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2020M1023932		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Hydroxychloroquine			S	Unknown			Not Reported

Immune Reconstitution Inflammatory Syndrome; Whipple'S Disease	Methylprednisolone	S	Unknown	Mylan
	Celecoxib	C	Unknown	Mylan
	Cyclobenzaprine	C	Unknown	Mylan
	Immunoglobulin /07494701/	C	Intravenous (not otherwise specified)	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17509914	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-06905		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic;	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular		Not Reported

	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Myochrysine	S	Parenteral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Prednisolone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Ciclosporin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17510338	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197076		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Methotrexate			S	Subcutaneous			Barr
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

	Sulfasalazine	S	Unknown	2000 Milligram Daily;	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17511324	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198114		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514071	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563594		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Minocycline	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514072	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563684		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514075	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563709		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Fatigue; Pain; Rheumatoid Arthritis; Swelling	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Prednisone			S	Unknown			Not Reported
	Cimzia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514081	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563795			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514088	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563821			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Arthritis	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514090	EXPEDITED (15-DAY)		DS	CA-ROCHE-2563708		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Bupropion			C				Not Reported
	Esomeprazole			C				Not Reported
	Folic Acid			C				Not Reported
	Levothyroxine			C				Not Reported
	Naproxen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514110	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564021		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Dysphonia; Dyspnoea; Odynophagia; Product Use In Unapproved Indication; Rheumatoid Arthritis; Stridor	Rituximab			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Mar-2020	17514113	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563829		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Rituxan			S	Intravenous drip	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2020	17511813	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2020-010743			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Thrombotic Stroke; Transient Ischaemic Attack	Atorvastatin			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Aurobindo
	Rivaroxaban			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2020	16749699	EXPEDITED (15-DAY)		OT	PHHY2019DE192163			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Ramipril			S	Oral	2 Df, Qd 1 Dosage Form, Bid (1-0-1)		Not Reported
	Ramipril			S				Not Reported
	Omeprazole			S	Oral	2 Df, Qd 1 Dosage Form, Bid (1-0-1)		Novartis
	Omeprazole			S				Novartis
	Sildenafil			S	Unknown	60 Mg, Qd		Not Reported
	Eliquis			S	Unknown	2 Df, Qd 1 Dosage Form, Bid (1-0-1)		Not Reported
	Eliquis			S	Unknown	2.5 Mg, Bid		Not Reported
	Lyrica			S	Unknown	3 Df, Qd 1 Dosage Form, Tid (1-1-1)		Not Reported
	Spasmolyt			S	Unknown	1 Df, Qd (15 (Unit Unspecified)		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd		Not Reported
	Quensyl			S	Unknown	2 Df, Qd 1 Dosage Form,		Not Reported

				Bid (1-0-1)		
	Roactemra		S	Unknown	162 Mg, Qwk	Not Reported
	Roactemra		S	Subcutaneous	162 Mg, Qwk	Not Reported
	Roactemra		S	Subcutaneous	162 Mg, Qwk	Not Reported
	Volibris		S	Unknown	Unk	Not Reported
	Volibris		S	Oral	1 Df, Qd	Not Reported
	Volibris		S	Oral	30 Mg, Qd	Not Reported
	Ambrisentan		S	Unknown	30 Mg, Qd	Not Reported
	Ambrisentan		S	Unknown	1 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	13053105	EXPEDITED (15-DAY)		OT	CA-ROCHE-1870952		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	15332459	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176746		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	15388757	EXPEDITED (15-DAY)		OT	CA-ROCHE-2182492		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Cortisone	S	Unknown	Not Reported
	Apo-Folic Acid	S	Unknown	Not Reported
	Apo-Folic Acid	S	Oral	Not Reported
	Apo-Folic Acid	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Fosamax	S	Oral	Not Reported
	Fosamax	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Topicorte	S	Subcutaneous	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported

Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Stelara	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported
Paracetamol	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Topicort Lp	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Cetirizine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported

	Golimumab	S	Unknown		Not Reported
	Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	15438204	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190752			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Dosage Form: Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
	Sulfasalazine			C	Unknown	Dosage Form: Not Specified		Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown	Tablet Extended Release		Not Reported
	Bupropion			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	15841668	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018134129		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Off Label Use; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Celebrex			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	10 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	50 Milligram, Bid		Not Reported
	Clindamycin Hcl			S	Unknown	Unk		Not Reported
	Lopressor			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Keflex [Cefalexin]			S	Unknown	Unk		Not Reported
	Cephalexin [Cefalexin]			S	Unknown	Unk		Not Reported
	Enalapril			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Hctz			S	Unknown	Unk		Not Reported
	Hydralazine Hydrochloride			S	Unknown	Unk		Not Reported
	Levaquin			S	Unknown	Unk		Not Reported
	Losartan			S	Unknown	Unk		Not Reported
	Metoprolol Tartrate			S	Unknown	Unk		Not Reported

	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Enalapril Maleate	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Losartan Potassium	S	Unknown	Unk	Not Reported
	Isoniazid	S	Unknown	Unk	Not Reported
	Cephalexin Monohydrate	S	Unknown	Unk	Not Reported
	Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk	Not Reported
	Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.	S	Unknown	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Atenolol	C		Unk	Not Reported
	Colchicine	C		Unk	Not Reported
	Coversyl [Perindopril Erbumine]	C		Unk	Not Reported
	Leucovorin [Folinic Acid]	C		Unk	Not Reported
	Levothyroxine Sodium	C		Unk	Not Reported
	Ranitidine	C		Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	16242893	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1269		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Methotrexate (Trade Name			S	Unknown			Not Reported

Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Enzyme Increased; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Unknown)			
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Ciprofloxacin	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Enalapril Maleate	S	Unknown	Not Reported
	Pantoprazole Magnesium	S	Unknown	Not Reported
	Hydrochlorothiazide	S	Unknown	Not Reported
	Losartan Potassium	S	Unknown	Not Reported
	Isoniazid	S	Unknown	Not Reported
	Cephalexin Monohydrate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Lopressor	S	Unknown	Not Reported
	Penicillin G	S	Unknown	Not Reported
	Penicillin G (2-Amino-4-Methoxy-6-Methylpyrim)	S	Unknown	Not Reported
	Plaquenil S	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Biaxin	S	Unknown	Not Reported
	Cephalexin	S	Unknown	Not Reported
	Clindamycin Hydrochloride	S	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Colchicine	C	Unknown	Not Reported
	Coversyl	C	Unknown	Not Reported

Leucovorin	C	Unknown	Not Reported
Levothyroxine Sodium	C	Unknown	Not Reported
Ranitidine	C	Unknown	Not Reported
Atenolol	C	Unknown	Not Reported
Gold	C	Unknown	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Iron Sucrose	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	16858320	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-SHIRE-SK201931249			Unknown	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Maternal Exposure During Pregnancy; Oligohydramnios; Premature Baby	Human Normal Immunoglobulin			S	Transplacental	Unk		Shire
	Human Normal Immunoglobulin			S				Shire
	Hydrocortisone			S	Transplacental	Unk		Not Reported
	Hydrocortisone			S				Not Reported
	Vitamin K Nos			S	Transplacental	Unk		Not Reported
	Vitamin K Nos			S				Not Reported
	Bisulepin			S	Transplacental	Unk		Not Reported
	Bisulepin			S				Not Reported
	Nadroparine			S	Transplacental	Unk		Not Reported
	Nadroparine			S				Not Reported
	Etamsylate			S	Transplacental	Unk		Not Reported
	Privigen			S	Transplacental	Unk		Not Reported
	Privigen			S	Transplacental	Unk		Not Reported
	Privigen			S	Transplacental			Not Reported
	Flebogamma Dif [Immunoglobulin Human Normal]			S	Transplacental	Unk		Not Reported
	Flebogamma Dif [Immunoglobulin Human Normal]			S				Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported

Dexamethasone	S	Transplacental	Unk	Not Reported
Metoprolol Tartrate	S	Transplacental	Unk	Not Reported
Metoprolol Tartrate	S			Not Reported
Potassium Chloride	S	Transplacental	Unk	Not Reported
Potassium Chloride	S			Not Reported
Prednisone	S	Transplacental	Unk	Not Reported
Prednisone	S	Transplacental	Unk	Not Reported
Vitamin B Complex	S	Transplacental	Unk	Not Reported
Vitamin B Complex	S			Not Reported
Albumin	S	Transplacental	Unk	Not Reported
Albumin	S			Not Reported
Paracetamol	S	Transplacental	Unk	Not Reported
Paracetamol	S			Not Reported
Folic Acid	S	Transplacental	Unk	Not Reported
Folic Acid	S			Not Reported
Methylprednisolone Sodium Succinate	S	Transplacental	Unk	Not Reported
Methylprednisolone Sodium Succinate	S	Transplacental	Unk	Not Reported
Penicillin G [Benzylpenicillin Sodium]	S	Transplacental	Unk	Not Reported
Penicillin G [Benzylpenicillin Sodium]	S			Not Reported
Dicynon	S	Transplacental	Unk	Not Reported
Dicynon	S			Not Reported
Cefixime	S	Transplacental	Unk	Not Reported
Cefixime	S			Not Reported
Vitamin D [Colecalciferol]	S	Transplacental	Unk	Not Reported
Vitamin D [Colecalciferol]	S			Not Reported
Ornidazole	S	Transplacental	Unk	Not Reported
Ornidazole	S			Not Reported
Omeprazole	S	Transplacental	Unk	Not Reported
Omeprazole	S			Not Reported
Bisoprolol Fumarate	S	Transplacental	Unk	Not Reported
Bisoprolol Fumarate	S			Not Reported

	Fluconazole	S	Transplacental	Unk	Not Reported
	Fluconazole	S			Not Reported
	Magnesium Lactate	S	Transplacental	Unk	Not Reported
	Magnesium Lactate	S			Not Reported
	Cefotaxime	S	Transplacental	Unk	Not Reported
	Cefotaxime	S	Transplacental	Unk	Not Reported
	Calcium Carbonate	S	Transplacental	Unk	Not Reported
	Calcium Carbonate	S			Not Reported
	Vulmizolin	S	Transplacental	Unk	Not Reported
	Vulmizolin	S			Not Reported
	Aminomethylbenzoic Acid	S	Transplacental	Unk	Not Reported
	Aminomethylbenzoic Acid	S			Not Reported
	Hydroxychloroquine	S	Transplacental	Unk	Not Reported
	Hydroxychloroquine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17240953	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019056593		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram Solution		Not Reported
	Orencia			S		Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Kevzara			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported

Methotrexate	S	Oral	Unk		Not Reported
Methotrexate	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S		Unk		Not Reported
Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
Folic Acid	C				Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Once Daily (Qd)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17462267	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202002000962			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Drug-Induced Liver Injury; Hepatic Steatosis; Pyrexia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Prednisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17514982	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197337		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17514985	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197060			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515012	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197749		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported

Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515017	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197343			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate Sodium			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Pseudoephedrine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515025	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197995		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis	Methotrexate			S	Unknown			Barr

Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis	Cimzia Single-Use Prefilled Syringe		S	Subcutaneous		Not Reported
	Actemra		S	Unknown		Not Reported
	Enbrel		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate		C	Unknown		Not Reported
	Ergocalciferol		C	Unknown		Not Reported
	Estrogel		C	Unknown	1.8 Percent Daily;	Not Reported
	Furosemide		C	Unknown		Not Reported
	Morphine		C	Unknown		Not Reported
	Potassium Chloride		C	Unknown	1500 Milligram Daily;	Not Reported
	Valsartan		C	Unknown	320 Milligram Daily;	Not Reported
	Xalatan		C	Ophthalmic	50 Microgram Daily;	Not Reported
	Zingiber Officinale		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515026	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197604		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515117	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197685		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Injection Site Reaction; Meningitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515196	EXPEDITED (15-DAY)		OT	CA-ROCHE-2563785		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515200	EXPEDITED (15-DAY)		OT	GB-MICRO LABS LIMITED-ML2020-00579		29 YR	Male	GBR

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

Drug Ineffective	Atorvastatin	S		Micro Labs
	Apixaban	S		Micro Labs
	Rivaroxaban	S		Not Reported
	Hydroxychloroquine	S		Not Reported
	Clopidogrel	S		Not Reported
	Warfarin	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515331	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197063		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	5 Milligram Daily;		Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous	2 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17515947	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED-2020SP003312		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disease Progression; Pseudomonas Infection; Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	60 Milligram, Unknown		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Dapsone			S	Unknown	Unk		Not Reported

	Rituximab			S	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17516183	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020100139			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis; Synovitis	Methotrexate Sodium			S				Pfizer
	Arava			S				Not Reported
	Humira			S		Once Weekly		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17516870	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001360			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17517057	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200243755		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fall; Interstitial Lung Disease; Treatment Failure	Stelara			S	Subcutaneous	4.0 Years		Not Reported
	Bromocriptine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Colchicine			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Gold			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Enbrel	S	Unknown		Not Reported
	Mercaptopurine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Pamidronate Disodium	S	Unknown		Not Reported
	Tenoxicam	S	Unknown		Not Reported
	Xeljanz	S	Unknown	2 Every 1 Days	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17517125	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001361			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17517277	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001247			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17518881	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198199		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Off Label Use; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Losartan			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17518920	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001368			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519592	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2020M1024194		77 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Depression; Drug Interaction; Dyspnoea; Feeling Abnormal; Head Discomfort; Near Death Experience; Palpitations; Reading Disorder	Fluoxetine			S		1 Df, Qd		Not Reported
	Plaquenil /00072602/			S		200 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519909	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07754			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cetirizine			S	Unknown	Unknown		Not Reported

	Cimzia	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Unknown,	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Folic Acid	S	Unknown	Unknown	Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Orencia	S	Subcutaneous	Unknown	Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519910	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07738		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported

Humira	S	Subcutaneous	Unknown,Solution Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Intravenous (not otherwise specified)			Not Reported
Methotrexate	S	Subcutaneous			Not Reported
Methotrexate	S	Oral			Not Reported
Methotrexate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Plaquenil	S	Unknown			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Xeljanz	C	Unknown	Unknown		Not Reported
Hydroxychloroquine Sulfate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519917	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07767		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Etanercept			S	Subcutaneous			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown	Unknown		Not Reported
	Prednisone	S	Oral			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Winpred	S	Oral			Not Reported
	Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519921	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07797			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Etanercept			S	Unknown	Unknown		Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519967	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001365			Unknown	USA

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

Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S	Unk					Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519980	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001364			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519984	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001363			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519985	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001362			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519989	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001367			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519991	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001366			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17519999	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001369			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17520010	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001371			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2020	17520013	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001370			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	15632273	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105425		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	500 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
	Rituximab			S	Intravenous (not			Not Reported

					otherwise specified)					
	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	16085204	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05925		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Oral			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknwon Solution Subcutaneous		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported

Tocilizumab	S	Subcutaneous	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unknown		Not Reported
Desoximetasone	C	Unknown	Unknown		Not Reported
Methotrexate	C	Oral			Not Reported
Methotrexate	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	16191539	EXPEDITED (15-DAY)		HO, LT, OT	JP-GLAXOSMITHKLINE-JP2019JPN049251		30 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Aplasia Pure Red Cell; Haemolysis	Belimumab			S	Intravenous drip	400mg, Once In Every Two Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	400mg, Once In Every Four Weeks		Glaxosmithkline
	Plaquenil			S	Oral	200mg, 400mg Alternate Day		Not Reported
	Prograf			S	Oral	3 Mg, 1d		Not Reported
	Predonine Tablets			C		14 Mg, 1d		Not Reported
	Predonine Tablets			C		14 Mg, 1d		Not Reported
	Predonine Tablets			C		13 Mg, 1d		Not Reported
	Predonine Tablets			C		12 Mg, 1d		Not Reported
	Predonine Tablets			C		22 Mg, 1d		Not Reported
	Predonine Tablets			C		32 Mg, 1d		Not Reported
	Predonine Tablets			C		45 Mg, 1d		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	16237399	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018386187		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Off Label Use; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Celebrex			S	Unknown	Unk		Pfizer
	Ciprofloxacin			S	Unknown	Unk		Pfizer
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	10 Milligram, 1/Week		Pfizer
	Methotrexate Sodium			S	Subcutaneous	10 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	10 Milligram, 1/Week		Pfizer
	Pantoprazole			S		Unk		Pfizer
	Xeljanz			S	Oral	50 Mg, Bid		Pfizer
	Clindamycin Hcl			S	Unknown	Unk		Pfizer
	Lopressor			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Keflex [Cefalexin]			S	Unknown	Unk		Not Reported
	Cephalexin [Cefalexin]			S		Unk		Not Reported
	Enalapril			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Hctz			S	Unknown	Unk		Not Reported
	Hydralazine Hydrochloride			S	Unknown	Unk		Not Reported
	Levaquin			S	Unknown	Unk		Not Reported
	Losartan			S	Unknown	Unk		Not Reported
	Metoprolol Tartrate			S		Unk		Not Reported
	Moxifloxacin Hydrochloride			S	Unknown	Unk		Not Reported
	Pariet			S	Unknown	Unk		Not Reported
	Enalapril Maleate			S		Unk		Not Reported

	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Losartan Potassium	S	Unknown	Unk	Not Reported
	Isoniazid	S	Unknown	Unk	Not Reported
	Cephalexin Monohydrate	S	Unknown	Unk	Not Reported
	Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk	Not Reported
	Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.	S	Unknown	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Atenolol	C		Unk	Not Reported
	Colchicine	C		Unk	Not Reported
	Coversyl [Perindopril Erbumine]	C		Unk	Not Reported
	Leucovorin [Folinic Acid]	C		Unk	Not Reported
	Levothyroxine Sodium	C		Unk	Not Reported
	Ranitidine	C		Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	16438993	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2017-04887			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Contraindicated Product Administered; Drug Ineffective; Encephalitis; Hypoaesthesia; Off Label Use	Etanercept			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Humira	S	Subcutaneous	Unknown		Not Reported
Hydroxychloroquine	S	Oral			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Leflunomide	S	Oral			Not Reported
Methotrexate	S	Unknown			Not Reported
Orencia	S	Unknown	Unknown		Not Reported
Orencia	S				Not Reported
Acetaminophen	C	Unknown	Unknown		Not Reported
Pregabalin	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	16838864	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27398		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Off Label Use; Pneumonia; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Lidocaine Hydrochloride			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Unknown	Unknown		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unknown		Not Reported

	Plaquenil	S	Unknown	Unknown		Not Reported
	Xeljanz	S	Oral			Not Reported
	Cephalexin	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518377	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559714			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Other			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518870	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001248			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518875	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020005			Female	CAN

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

Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Nephrolithiasis; Somnolence; Visual Impairment	Orencia	S	Unknown		Bristol Myers Squibb
	Acetaminophen	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Mg, 2 Every 2 Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram	Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown		Not Reported
	Celebrex	C	Oral	200 Milligram, Bid	Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported
	Synthroid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518925	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564559		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Etanercept	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Parenteral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518935	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564545		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported

	Methotrexate		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17518982	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198212			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Pseudoephedrine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab		S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519028	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001249			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519034	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197395		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram Daily;		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519069	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001250			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Stillbirth	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519160	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001398			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Stillbirth	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519161	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001397			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Stillbirth	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519188	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001393			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519189	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001392			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519200	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001390			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519202	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001394			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519203	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001391			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519483	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001381			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519484	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001380			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519489	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001379			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519490	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001389			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519495	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001383			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519498	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001382			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519533	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2020-07587			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Prescribed Underdose; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Apo-Naproxen			S	Unknown	Unknown		Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution, Unknown		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Immune Globulin (Immunoglobulins Nos)			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Orencia	S	Unknown	Unknown		Not Reported
Sulfasalazine	S	Oral			Not Reported
Triamcinolone	S	Intra-articular	Unknown		Not Reported
Triamcinolone	S	Unknown	Unknown		Not Reported
Folic Acid	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519538	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197730			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Norflex [Orphenadrine Citrate]			C	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C	Unknown			Not Reported
	Loperamide			C	Unknown			Not Reported
	Omnaris			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Plantago Ovata			C	Unknown			Not Reported
	Darifenacin			C	Unknown			Not Reported

Synthroid	C	Unknown	Not Reported
Vagifem	C	Vaginal	Not Reported
Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519544	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001252			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cleft Lip And Palate; Foetal Exposure During Pregnancy	Hydroxychloroquine			S	Transplacental	Unk		Concordia
	Prednisone			S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519545	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001253			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Pleural Effusion; Pneumonia	Hydroxychloroquine			S	Transplacental	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519551	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001254			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Rectal Haemorrhage	Hydroxychloroquine			S	Transplacental	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519651	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1196061		30 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Micofenolato De Mofetilo			S	Oral	500 Mg 12 Hours		Teva

	(7330lm)				
	Colchimax (Colchicine/Dicycloverine Hydrochloride)	S	Oral	0.5 Mg 24 Hours	Not Reported
	Dolquine 200 Mg Comprimidos, 30 Comprimidos	S	Oral	200 Mg 12 Hours	Not Reported
	Rituximab (2814a)	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519653	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1197404			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519654	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198000			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519660	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198122			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Dermatitis Allergic; Hepatic Cirrhosis; Hypersensitivity; Psoriasis; Rash Papular; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S		400 Milligram Daily;		Not Reported
	Celebrex			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Sulfanilamide			S	Unknown			Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519699	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198638			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Product Effect Decreased	Methotrexate			S	Intramuscular			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Apo-Leflunomide	S	Oral	10 Milligram Daily;	Not Reported
Acetylsalicylic Acid	C	Unknown		Not Reported
Asa	C	Unknown		Not Reported
Calcium	C	Unknown		Not Reported
Lantus	C	Subcutaneous		Not Reported
Lozide	C	Unknown		Not Reported
Metformin	C	Unknown		Not Reported
Naproxen	C	Unknown		Not Reported
Naproxen	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Ramipril	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519737	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07727			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling; Malaise; Nodule; Off Label Use; Pain; Product Dose Omission; Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling; Systemic Lupus Erythematosus Rash; Tenosynovitis; Therapeutic Response	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unknown,		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown	Unknown		Not Reported

Decreased; Tooth Disorder; Tooth Infection; Weight Decreased	Naproxen		C	Unknown	Unknown	Not Reported
	Risedronate Sodium		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17519854	EXPEDITED (15-DAY)		OT	NVSC2020CA064906			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective	Neoral			S	Oral	20 Mg		Novartis
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Plaquenil			S	Oral	20 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17521749	EXPEDITED (15-DAY)		OT	CA-SA-2020SA060110		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Topicort			S	Cutaneous	Unk		Sanofi
	Actemra			S				Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C				Not Reported
	Arava			S	Oral			Sanofi
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S				Not Reported
	Alendronate Sodium			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Methotrexate			S	Oral			Not Reported
	Orencia			S				Not Reported

Phthalylsulfathiazole	S				Not Reported
Prednisone	S				Not Reported
Cetirizine Hydrochloride	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Oral	2 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17521788	EXPEDITED (15-DAY)		OT	CA-SA-2019SA130309		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Eye Disorder; Psoriasis; Rash; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S		Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desvenlafaxine Succinate			C				Not Reported
	Prednisone			C				Not Reported
	Quetiapine Fumarate			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17521819	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020103635		70 YR	Female	CAN

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

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Off Label Use; Product Use Issue; Skin Reaction; Synovitis; White Blood Cell Count Decreased	Enbrel	S	Unknown	Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Weekly	Pfizer
	Sulfasalazine	S	Oral	1 G, 2x/Day	Pfizer
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, 1x/Day	Not Reported
	Leflunomide	S	Unknown	Unk, 1x/Day	Not Reported
	Orencia	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17522043	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2020101975		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Apo-Prednisone			S	Unknown	50 Mg, Unk		Not Reported
	Apo-Prednisone			S	Unknown	25 Mg, 1x/Day		Not Reported
	Apo-Prednisone			S	Oral	3 Mg, 1x/Day		Not Reported
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Gold Radioactive Colloidal			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, 1x/Day		Not Reported

Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 1x/Day	Not Reported
Indometacin	S	Unknown	Unk	Not Reported
Indomethacin	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil	S	Unknown	400 Mg, 1x/Day	Not Reported
Prednisone	S	Oral	3 Mg, 1x/Day	Not Reported
Prednisone	S	Oral	50 Mg, Weekly	Not Reported
Prednisone	S	Oral	25 Mg, 1x/Day	Not Reported
Prednisone	S		50 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Cymbalta	C	Unknown	30 Mg, 1x/Day	Not Reported
Folic Acid	C	Oral	Unk Unk, Weekly	Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17524186	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1198464			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17524188	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198197		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cystitis; Dyspnoea; Musculoskeletal Disorder; Pain In Extremity; Pneumonia	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17524511	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198573			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown	20 Milligram Daily;		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17524518	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-		59 YR	Female	CAN

1198591

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Diabetes Mellitus; Flushing; Gastrointestinal Disorder; Headache; Hepatic Steatosis; Herpes Zoster; Hypertension; Liver Function Test Increased; Nervous System Disorder; Off Label Use; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Vomiting	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Gadolinium-Zeolite Xanthan Gum Complex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Escitalopram Oxalate			C	Oral	10 Milligram Daily;		Not Reported
	Humira			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Oral	40 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	5 Milligram Daily;		Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526155	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-07599		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Impaired	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Subcutaneous	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported

Gastric Emptying; Influenza; Off Label Use; Osteoarthritis; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Azathioprine	S	Unknown	Unknown	Not Reported
	Ciclosporin	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Intramuscular	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown,	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unknown	Not Reported
	Sulfasalazine	S	Oral	Unknown	Not Reported
	Xeljanz	S	Oral		Not Reported
	Meloxicam	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526171	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-07695		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Unknown			Not Reported

Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Actemra	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Alendronic Acid	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Codeine	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Myochrysine	S	Intramuscular	Solution Intramuscular	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S			Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported

	Prednisone		C	Unknown	Unknown	Not Reported
	Xeljanz		C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526218	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07590			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Morphine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526220	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-07630		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off	Infliximab			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Actemra			S				Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis; Treatment Failure	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia		S	Subcutaneous		Not Reported
	Prednisone		S	Unknown		Not Reported
	Rituximab		S	Unknown	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Xeljanz		S	Oral		Not Reported
	Gabapentin		C	Unknown		Not Reported
	Acetaminophen		C	Unknown		Not Reported
	Cetirizine Hydrochloride		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526909	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198107			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17526918	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198570			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	13855498	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070302		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Off Label Use; Skin Warm	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	14735736	EXPEDITED (15-DAY)		OT	CA-SA-2018SA098039			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Celecoxib			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported

	Orencia	S	Unknown	Unk Unk,Unk	Not Reported
	Bifidobacterium Bifidum	C	Unknown	Align Digestive Aid	Not Reported
	Loperamide	C	Oral	2mg/1-2-Tabs 4x Per Day; Ongoing	Not Reported
	Pantoprazole	C	Unknown	Unk Unk,Tid	Not Reported
	Xeljanz	C	Oral	5 Mg,Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	14747168	EXPEDITED (15-DAY)		OT	CA-SA-2018SA098040		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20.0 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Erythromycin			S	Unknown	Unk, Unk		Sanofi
	Erythromycin			S	Unknown	Unk		Sanofi
	Risedronate Sodium			S	Oral	35 Mg, Qw		Not Reported
	Methotrexate			S	Oral	22.5 Mg,Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400.0 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S		Unk, Unk		Not Reported
	Marijuana			C	Unknown	Unk		Not Reported
	Wellbutrin			C	Unknown	300 Mg, Qd		Not Reported
	Celebrex			C	Unknown	200 Mg, Bid		Not Reported
	Ergocalciferol			C	Unknown	4000.0 Iu, Qd		Not Reported
	Bupropion			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	15350172	EXPEDITED (15-DAY)		OT	CA-ROCHE-2179240			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	16312624	EXPEDITED (15-DAY)		OT	CA-SA-2019SA130280		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Erythromycin			S	Unknown	Unk		Sanofi
	Erythromycin			S	Unknown	Unk		Sanofi
	Sulfasalazine			S				Not Reported
	Methotrexate			S	Oral	22.5 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Not Reported
	Orencia			S		Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Celebrex			C	Unknown	200 Mg, Bid		Not Reported
	Ergocalciferol			C	Unknown	4000 Iu, Qd		Not Reported
	Marijuana			C				Not Reported
	Risedronate			C	Oral	35 Mg, Qw		Not Reported
	Wellbutrin			C		300 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17259828	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514035		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17434256	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202002000843			Unknown	USA

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

Drug-Induced Liver Injury; Hepatitis Cholestatic; Pneumonia; Rash; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Hydroxychloroquine	S	Unk		Concordia
	Azathioprine	S	Unk		Not Reported
	Oseltamivir	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17448695	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP007808			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Localised Infection; Skin Discolouration; Skin Exfoliation; Soft Tissue Necrosis	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Methotrexate			C	Unknown	Unk		Not Reported
	Prednisone			C	Intramuscular	80 Mg, Unk		Not Reported
	Sulfasalazine			C	Oral	1500 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17485746	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202002001107			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Encephalitis; Meningitis; Treatment Failure; Unevaluable Event	Hydroxychloroquine			S	Oral	200 Mg, Qd (1 And 1/2 Tablets), Tablet		Concordia
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk, On And Off		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

	Sulfasalazine	C	Unk	Not Reported
	Enbrel	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17498908	EXPEDITED (15-DAY)		DE, HO	NVSC2020US060102		59 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Failure	Trametinib			S	Oral	2 Mg, Qd		Novartis
	Hydroxychloroquine Sulfate			S	Oral	600 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17523978	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198588		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported

	Desoximetasone	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17523994	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020101881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Methotrexate Sodium			S	Subcutaneous	20 Mg, Once Weekly		Pfizer
	Actemra			S		300 Mg, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S		300 Mg, 1x/Day		Not Reported
	Orencia			S				Not Reported
	Simponi			S	Subcutaneous	1 Every 2 Months		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17524962	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198648			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529355	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198780		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate		S	Oral		Not Reported
	Xeljanz		S	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529545	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198768		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug Ineffective; Malaise; Night Sweats; Peripheral Swelling; Vomiting	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529557	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1199245		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fall; Femur Fracture	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous	200 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Atrovent			C				Not Reported
	Benztropine Mesylate			C				Not Reported
	Chlordiazepoxide			C				Not Reported
	Folic Acid			C				Not Reported
	Levomepromazine Maleate			C				Not Reported
	Methotrexate			C				Not Reported
	Pantoprazole			C				Not Reported
	Risedronate Sodium			C				Not Reported
	Salbutamol			C				Not Reported
	Trifluoperazine [Trifluoperazine Hydrochloride]]			C				Not Reported
	Zopiclone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529613	EXPEDITED (15-DAY)		LT, OT	CA-TEVA-2020-CA-1199352			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Indometacin			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn [Naproxen Sodium]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529648	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1199350		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Liver Disorder; Renal Disorder	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Hydroxychloroquine Sulfate			S	Oral	40 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529653	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198795		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Nasopharyngitis	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529761	EXPEDITED (15-DAY)		OT	NVSC2020CA065255		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg (Solution)		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution)		Not Reported
	Rituxan			S	Unknown	Unk (Solution)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	30 Mg/Kg		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw (1 Every 1 Weeks)		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported

	Xeljanz	C	Oral	5 Mg, Bid (2 Every 1 Days)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529893	EXPEDITED (15-DAY)		OT	CA-NAPPMUNDI-CAN-2020-0010681		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Dilaudid			S	Unknown	Unk		Purdue
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Acetaminophen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17529928	EXPEDITED (15-DAY)		OT	CA-NAPPMUNDI-CAN-2020-0010695		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fear Of Injection; Musculoskeletal Disorder; Pulmonary Sarcoidosis; Rheumatoid Arthritis	Morphine Sulfate			S	Unknown	Unk		Purdue
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Weekly		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17530605	EXPEDITED (15-DAY)		DE, HO, OT	CA-PFIZER INC-2020105703		70 YR	Male	CAN

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

Blister; Chills; Erythema; Fatigue; Hypotension; Klebsiella Infection; Leukopenia; Multiple Organ Dysfunction Syndrome; Odynophagia; Rash; Rash Vesicular; Skin Lesion; Thrombocytopenia; Varicella Zoster Virus Infection	Methotrexate Sodium	S	Unknown	2.5 Mg, 1x/Day	Pfizer
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 1x/Day	Not Reported
	Prednisone	S	Unknown	10 Mg, 1x/Day	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2020	17532248	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021341			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Headache; Tremor	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Oral	2.5 Milligram, Qd		Not Reported
	Methotrexate			C	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			C	Oral	15 Milligram, Qwk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Oral	40 Milligram, Qd		Not Reported

Tenofovir Disoproxil	C	Unknown	Unk		Not Reported
Tenofovir Disoproxil	C	Unknown	300 Milligram		Not Reported
Xeljanz	C	Unknown			Not Reported
Zopiclone	C	Unknown	7.5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	9421143	EXPEDITED (15-DAY)		OT	PHHY2013FR077105		57 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Antinuclear Antibody Positive; Bicytopenia; Dermatitis Psoriasiform; Dna Antibody; Drug Ineffective; Erythema; Evans Syndrome; General Physical Health Deterioration; Hypergammaglobulinaemia; Lupus Vasculitis; Lymphadenopathy; Pericarditis; Pyrexia; Scar; Skin Exfoliation; Skin Lesion; Subacute Cutaneous Lupus Erythematosus; Systemic Lupus Erythematosus	Omeprazole			S	Unknown	Unk		Novartis
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	10592296	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2014089242		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis;	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S				Amgen
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	200 Milligram, Bid		Not Reported

Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Insomnia; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Methotrexate	S	Unknown	Unk Unk, Qd	Not Reported
	Methotrexate	S			Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	14 Milligram, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk, Qmo	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk Unk, Bid	Not Reported
	Prednisone	S	Unknown	14 Milligram, Qd	Not Reported
	Dilaudid	C	Unknown	4 Milligram, Tid	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Furosemide	C	Unknown	Unk, Qd	Not Reported
	Hydromorph Contin	C	Unknown	18 Milligram, Tid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	11457175	NON-EXPEDITED		CA, DS, HO, OT	CA-AMGEN-CANSP2015088317		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Nail Operation; Onychomadesis; Onychomycosis	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	5 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Remicade	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Oral	Unk	Not Reported
Infliximab	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Arava	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	11512274	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2015094557		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported

Decreased	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram	Not Reported
	Rituxan	S	Unknown	1000 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Qwk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	10 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	11962064	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2012074066		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint;	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S				Amgen
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis			otherwise specified)		
	Actemra	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Aleve	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk Unk, Cyclical (1 Every Two Days)	Not Reported
	Leflunomide	S	Unknown	Unk Unk, Bid	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Plaquenil	C	Unknown	Unk	Not Reported
	Folic Acid	C	Subcutaneous	Unk	Not Reported
	Hcq	C		Unk	Not Reported
	Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	2 Dosage Form, Qd	Not Reported
	Insulin	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	2 Dosage Form, Bid	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	20 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12133375	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016018438		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Unevaluable Event	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Apo-Azathioprine			S	Unknown	100 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	50 Milligram		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Humira			S	Subcutaneous	400 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	5 Nanogram, Bid		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Apo-Minocycline			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk Unk, Qmo	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram, Qd	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	100 Milligram	Not Reported
Arava	S	Oral	20 Milligram, Qwk	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Methotrexate Sodium	S	Subcutaneous	25 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	20 Unk, Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Amoxil	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Clavulin	C		Unk	Not Reported
Amoxicillin Trihydrate And Clavulanate Potass	C	Unknown	Unk	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk	Not Reported
Bcg Vaccine	C	Unknown	Unk	Not Reported
Adalimumab	C		Unk	Not Reported

	Amoxicillin Sodium And Clavulanate Potassium	C	Unknown	Unk	Not Reported
	Amoxicillin Sodium And Clavulanate Potassium	C	Unknown	Unk	Not Reported
	Risedronate	C	Oral	35 Milligram, Qwk	Not Reported
	Amoxicillin	C		Unk	Not Reported
	Amoxil [Amoxicillin Trihydrate]	C	Unknown	Unk	Not Reported
	Hydroxychloroquine	C	Subcutaneous	400 Milligram	Not Reported
	Hydroxychloroquine	C	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine	C	Unknown	100 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12146308	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016130747		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Pantoloc			S	Unknown	40 Milligram, Qd		Pfizer
	Pantoloc			S	Unknown	40 Milligram, Qd		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Etanercept			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Q2weeks		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, 1/Week		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, 1/Week		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, 1/Week		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Q2weeks		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Q2weeks		Pfizer
	Methotrexate Sodium			S	Oral	Unk, Q2weeks		Pfizer
	Sulfasalazine			S	Oral	500 Milligram, Bid		Pfizer
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Pfizer
	Sulfasalazine			S	Oral	500 Milligram, Bid		Pfizer
	Pantoprazole Sodium Anhydrous			S		40 Mg, 1x/Day		Not Reported

Pantoprazole Sodium Sesquihydrate	S		40 Mg, 1x/Day	Not Reported
Apo-Folic Acid	S		5 Mg, 2x/Week	Not Reported
Apo-Folic Acid	S		5 Mg, 2x/Week	Not Reported
Co Atenolol	S		25 Milligram, Qd	Not Reported
Co Atenolol	S		20 Milligram, Qd	Not Reported
Atenolol	S		25 Mg, 1x/Day	Not Reported
Naprosyn	S	Oral	100 Milligram, Qd	Not Reported
Naprosyn	S	Oral	500 Milligram, Bid	Not Reported
Naprosyn	S	Oral	500 Mg, 2x/Day	Not Reported
Naprosyn	S	Oral	1000 Mg, 1x/Day	Not Reported
Naproxen	S	Oral	100 Milligram, Qd	Not Reported
Naproxen	S	Oral	500 Milligram, Qd	Not Reported
Palafer Cf	S	Unknown	Unk, Qd	Not Reported
Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil	S	Unknown	40 Milligram, Qd	Not Reported
Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
Pantoprazole Teva	S	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole Teva	S	Unknown	Unk	Not Reported
Ferrous Fumarate W/Folic Acid	S	Unknown	Unk Unk, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Arava	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	20 Mg, 1x/Day	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk, Qd	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S		Unk	Not Reported

Adalimumab	S	Subcutaneous	Unk	Not Reported
Abatacept	S		Unk	Not Reported
Ascorbic Acid	S		Unk, 1x/Day	Not Reported
Ascorbic Acid	S	Unknown	Unk, Qd	Not Reported
Ferrous Fumarate	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram, Bid	Not Reported
Folic Acid	S	Unknown	5 Milligram, 2/Week	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S		200 Mg, 2x/Day	Not Reported
Hydroxychloroquine Sulfate	S		40 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S		40 Mg, Unk	Not Reported
Ferrous Fumarate/Folic Acid	S		Unk, 1x/Day	Not Reported
Remicade	S		Unk	Not Reported
Naproxen Sodium	S		500 Mg, 2x/Day	Not Reported
Naproxen Sodium	S		1000 Mg, 1x/Day	Not Reported
Naproxen Sodium	S	Oral	500 Mg, 2x/Day	Not Reported
Naproxen Sodium	S	Oral	100 Mg, 2x/Day	Not Reported
Naproxen Sodium	S	Oral	1000 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S		400 Mg, Weekly	Not Reported
Hydroxychloroquine	S		40 Mg, Weekly	Not Reported
Palafer	S		Unk	Not Reported
Pantoprazole Sodium	S		40 Mg, 1x/Day	Not Reported
Celebrex	C	Oral	200 Milligram, Qd	Not Reported
Celebrex	C		Unk	Not Reported
Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
Celecoxib	C	Oral	Unk	Not Reported
Celecoxib	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12172769	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016029473		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Bone Hypertrophy; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Q4wk		Not Reported
	Actemra			S	Oral	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q4wk		Not Reported
	Orencia			S	Subcutaneous	Unk, Qwk		Not Reported
	Orencia			S	Vaginal	750 Milligram, Qmo		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Q3wk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Not Reported
	Sulfasalazine			S	Oral	2.5 Gram, Qd		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	7.5-12.5 Milligram, Weekly		Not Reported
	Methotrexate			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Qwk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Q3wk		Not Reported

Decreased; Treatment Failure	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Gabapentin	S	Oral	100 Milligram, Bid	Not Reported
	Omega-3	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Diphenoxylate	C		2.5/0.25 Milligram, Qd	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram 1-3 Tabs, Qhs	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram	Not Reported
	Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
	Vitamin D	C		400 Unit, Qd	Not Reported
	Actonel	C		36 Mg, Qwk	Not Reported
	Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, (Every Four Weeks)	Not Reported
	Aclasta	C		750 Milligram, Qmo	Not Reported
	Calcium	C		Unk	Not Reported
	Genteal	C		3m Use As Directed	Not Reported
	Tylenol	C	Oral	500 Mg 2 Tabs, Od	Not Reported
	Nexium	C		40 Milligram One Tab, Bid	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Milligram, Qhs	Not Reported
	Nasonex	C		2 Sprays Per Nostrils, Bid	Not Reported
	Percocet	C		1 Tab, 4-6h Prn For Pain	Not Reported
	Lomotil	C		2.5 Milligram, 3-4 Times/Day	Not Reported
	Lomotil	C		2.5 Milligram, Qd	Not Reported
	Docosahexaenoic Acid W/Eicosapentae	C	Unknown	Unk Unk, Qd	Not Reported
	Docosahexaenoic Acid W/Eicosapentae	C	Unknown	Unk, Q2wk	Not Reported
	D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported

Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Qd	Not Reported
Diphenoxylate Hydrochloride	C		Unk, Qd	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Bid	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C		1 Unk	Not Reported
Trazodone	C		Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
Loperamide Hydrochloride	C		2.5 Milligram	Not Reported
Ergocalciferol	C		400 International Unit, Qd	Not Reported
Perphenazine	C	Oral	10 Milligram	Not Reported
Tecta	C		40 Milligram, Qd	Not Reported
Vitamin E [Tocopherol]	C		Unk	Not Reported
Fergon	C		300 Milligram, Qd	Not Reported
Ascorbic Acid	C		Unk	Not Reported
Biotin	C		Unk	Not Reported
Cholecalciferol	C		Unk	Not Reported
Ferrous Fumarate	C		Unk	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Qd	Not Reported
Folic Acid	C		Unk	Not Reported
Pantoprazole	C		Unk	Not Reported
Retinol Palmitate	C		Unk	Not Reported
Thiamine Hydrochloride	C		Unk	Not Reported
Riboflavin	C		Unk	Not Reported
Vitamin A [Retinol]	C		Unk	Not Reported
Vitamin B3	C		Unk	Not Reported
Vitamin B1 [Thiamine]	C		Unk	Not Reported
Vitamin B12 [Cyanocobalamin]	C		Unk	Not Reported
Vitamin B6	C		Unk	Not Reported
Vitamin C [Ascorbic Acid]	C			Not Reported

Acetaminophen	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12316477	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054049			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Intravenous (not otherwise specified)	200 Milligram, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	2000 Milligram, Qmo		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Qd		Not Reported
	Folic Acid			S	Unknown	1 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12321534	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2016054557		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort;	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qd		Not Reported

Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Rash; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Actemra	S	Intravenous (not otherwise specified)	8 Milligram, Qmo	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qmo	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Apo-Hydroxyquine	S	Oral	400 Mg, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Milligram, Qwk	Not Reported
	Plaquenil	S	Oral	400 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	S	Oral	5 Milligram, Bid	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12430947	NON-EXPEDITED		OT	CA-AMGEN-CANSP2014016405		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Plaquenil			S	Unknown	Unk		Not Reported

Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S			Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Methadone	S	Unknown	Unk	Not Reported
	Rampril	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Xalatan	C	Ophthalmic	50 Microgram, Qd (50 Mcg 0.005% 1 Drop)	Not Reported
	Cosopt	C		Unk, Bid	Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
	Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
	Vitamin D	C		10000 Unit, Qwk	Not Reported

	Gravol Ginger	C		500 Milligram, As Needed	Not Reported
	Potassium Chloride	C	Unknown	1500 Milligram, Qd	Not Reported
	Morphine	C	Unknown	Unk Unk, As Necessary	Not Reported
	Dorzolamide Hcl And Timolol Maleate	C	Unknown	Unk Unk, Bid	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qwk	Not Reported
	Ergocalciferol	C	Unknown	Unk, Qd	Not Reported
	Zingiber Officinale	C	Oral	500 Milligram	Not Reported
	Estradiol	C		Unk, Tid	Not Reported
	Estrogel	C		0.6 Percent, Tid	Not Reported
	Estrogel	C	Unknown	1 Dosage Form, Qd	Not Reported
	Calcium	C		500 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	12685066	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016109223		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	100 Milligram		Not Reported
	Azathioprine			S	Unknown	100 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported

	Sulfasalazine	S	Unknown	Unk	Not Reported
	Apo Hydroxyquine	S	Unknown	400 Mg, Unk	Not Reported
	Apo-Azathioprine	S	Unknown	100 Milligram	Not Reported
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	25 Mg, Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Leflunomide	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	13251335	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006763		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Swelling; Therapeutic Product Effect	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	1.0 Df, Qd		Not Reported
	Pregabalin			S	Oral	Unk		Not Reported
	Piroxicam			S	Unknown	Unk		Not Reported
	Apo-Mycophenolate			S	Unknown	Unk		Novartis
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cellcept /01275102/			S	Unknown	Unk		Not Reported

Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Lyrica	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Intra-arterial	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	13890626	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP016769			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthritis; Chest Pain; Drug Ineffective; Fibromyalgia; Hla Marker Study Positive; Immunodeficiency; Kyphoscoliosis; Musculoskeletal Discomfort; Musculoskeletal Stiffness; Myofascial Pain Syndrome; Plantar Fasciitis; Somnolence;	Apo-Meloxicam			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Amitriptyline			S	Unknown	Unk		Apotex
	Mobicox			S	Unknown	Unk		Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Enbrel			S	Unknown	500 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

Spinal Osteoarthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Sulfasalazine		S	Unknown	Unk		Not Reported
	Folic Acid		C	Unknown			Not Reported
	Methotrexate		C	Unknown	Unk		Not Reported
	Naproxen		C	Unknown	Unk		Not Reported
	Pantoprazole		C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	14872540	EXPEDITED (15-DAY)		OT	PHHY2018CA005549			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	14921584	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044591			Female	CAN

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

Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection; White Blood Cell Count Decreased	Orencia	S	Intravenous (not otherwise specified)	750 Milligram	Bristol Myers Squibb
	Hydroxychloroquine Phosphate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	17.5 Milligram	Not Reported
	Meloxicam	S	Unknown		Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Actemra	S	Subcutaneous	160 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Mobicox	S	Unknown	Unk	Not Reported
	Humira	C	Subcutaneous	Unk	Not Reported
	Diclofenac	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intra-articular	80 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	15207382	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016054855			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Enbrel			S	Unknown	50 Mg, Unk		Amgen
	Arava			S	Oral	10 Mg, 2 Times/Wk		Not Reported

Arava	S	Oral	10 Mg, 3 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, 1 Every 2 Days	Not Reported
Arava	S	Oral	10 Mg, Qd 3 Months	Not Reported
Arava	S	Oral	200 Mg, 2 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, Unk	Not Reported
Arava	S	Unknown	200 Mg, 2 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, Q3wk	Not Reported
Arava	S	Unknown	10 Mg, Qd	Not Reported
Arava	S	Oral	10 Mg, Bid	Not Reported
Arava	S	Oral	10 Mg, Q3mo	Not Reported
Arava	S	Unknown	200 Mg, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	12.5 Mg, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	12.5 Mg, Qd	Not Reported
Methotrexate Sodium	S	Unknown	Unk 2 Year	Not Reported
Methotrexate Sodium	S	Intramuscular	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	200 Mg, Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Rituxan	S	Unknown	1000 Mg, Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported

Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Intramuscular	Unk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Unk	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	40 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Qwk	Not Reported
Methotrexate	S	Intramuscular	12.5 Mg, Qd	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	Unk Unk, 1 Every 2 Years	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	15415981	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187426		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Depression; Drug Dependence; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Apo-Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	15486757	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016023969		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Enbrel			S	Unknown	Unk		Amgen
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported
	Zostavax			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Zostavax	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Unk	Not Reported
	Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Voltaren	C	Unknown	100 Milligram, Qd	Not Reported
	Cortisone	C		10 Milligram, Qd	Not Reported
	Cortisone	C	Oral	Unk	Not Reported
	Cortisone	C	Subcutaneous	Unk	Not Reported
	Desoximetasone	C	Oral	10 Milligram, Qd	Not Reported
	Desoximetasone	C	Unknown	10 Milligram, Qd	Not Reported
	Desoximetasone	C	Subcutaneous	Unk	Not Reported
	Diclofenac	C	Unknown	100 Milligram, Qd	Not Reported
	Diclofenac	C	Unknown	100 Milligram	Not Reported
	Diclofenac	C	Subcutaneous	100 Milligram	Not Reported
	Cortisone Acetate	C	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	10 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	Unk (2 Every 1 Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	16174170	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019151161		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Contraindicated Product Administered; Cough;	Pantoprazole			S	Unknown	Unk		Pfizer
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Pfizer
	Celebrex			S	Unknown	Unk		Pfizer
	Ciprofloxacin			S	Unknown	Unk		Pfizer
	Clindamycin Hcl			S	Unknown	Unk		Pfizer

Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Methotrexate Sodium	S	Subcutaneous	10 Milligram, 1/Week	Pfizer
	Avelox	S	Unknown	Unk	Not Reported
	Keflex [Cefalexin]	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Biaxin	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Enalapril Maleate	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hctz	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Losartan Potassium	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Penicillin G [Benzylpenicillin]	S	Unknown	Unk	Not Reported
	Lopressor	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Cephalexin Monohydrate	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Cipro [Ciprofloxacin]	S	Unknown	Unk	Not Reported
	Cipro [Ciprofloxacin]	S	Unknown	Unk	Not Reported
	Penicillin [Benzylpenicillin]	S	Unknown	Unk	Not Reported
	Isoniazid	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
	Hydroxychloroquine	C		Unk	Not Reported

	Hydroxychloroquine Sulfate	C		Unk		Not Reported
	Cipro [Ciprofloxacin]	C	Unknown	Unk		Not Reported
	Cipro [Ciprofloxacin]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	16697992	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2884328-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug-Induced Liver Injury	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17395700	EXPEDITED (15-DAY)		OT	NVSC2020CN032994		26 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Placenta Praevia; Premature Delivery; Systemic Lupus Erythematosus; Therapy Non-Responder	Prednisone			S	Unknown	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Unknown	Unk (3 Day Shock Therapy)		Not Reported
	Alfacalcidol			S	Unknown	Unk		Not Reported
	Vita-D			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17449223	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007791		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Off	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Subcutaneous	40 Mg, Unk		Apotex

Label Use; Oral Discomfort; Treatment Failure; Uveitis	Apo-Leflunomide	S	Unknown	Unk	Apotex
	Adalimumab	S	Subcutaneous	40 Mg, Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	10 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tofacitinib	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Kevzara	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	10 Mg, Unk	Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17449475	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1188488		50 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Back Disorder; Blood Albumin Decreased; C-Reactive	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous	3.5714 Milligram Daily;		Barr

Protein Increased; Condition Aggravated; Diverticular Perforation; Diverticulum; Drug Ineffective; Drug Intolerance; Hand Deformity; Headache; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphadenopathy; Musculoskeletal Stiffness; Neck Mass; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Thrombocytosis	Apo-Prednisone	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	7.1429 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Naprosyn E	S	Unknown	1000 Milligram Daily;	Not Reported
	Orencia	S	Subcutaneous	17.8571 Milligram Daily;	Not Reported
	Orencia	S	Sunconjunctival		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Methotrexate	S	Subcutaneous		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Lovastatin	C	Unknown		Not Reported
	Metoprolol	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Naproxen Sodium	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Rosuvastatin	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Tramadol Hydrochloride	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17488215	EXPEDITED (15-DAY)		OT	NVSC2020CA054557			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Uveitis	Cosentyx			S	Unknown	Unk		Novartis
	Humira			S	Subcutaneous	Unk		Not Reported

Apo Hydroxychloroquine	S	Unknown	400 Mg		Not Reported
Otezla	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Stelara	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	2 G		Not Reported
Cimzia	S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17491286	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008190		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Leflunomide			S	Unknown	Unk, Unknown		Apotex
	Enbrel			S	Unknown	Unk, Unknown		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk, Unknown		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Rituxan			S	Unknown	Unk, Unknown		Not Reported
	Rituximab			S	Unknown	Unk, Unknown		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17507283	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008205			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Dermatitis Allergic; Drug Ineffective; Drug Intolerance; Hepatotoxicity; Osteoarthritis;	Leflunomide			S	Oral	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Urticaria	Plaquenil /00072602/	S	Oral	200 Mg, Bid		Not Reported
	Sulfasalazine	S	Unknown	750 Mg, Qd		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
	Hydrochlorothiazide W/Lisinopril	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17528339	EXPEDITED (15-DAY)		OT	GB-ABBVIE-20K-167-3311302-00			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dactylitis; Drug Ineffective; Dry Skin; Emphysema; Hypoaesthesia; Hypoaesthesia; Joint Injury; Joint Swelling; Joint Swelling; Nausea; Paraesthesia; Psoriatic Arthropathy; Rash; Rheumatoid Nodule; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral	10mg To 15mg		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cosentyx			S	Intramuscular			Not Reported
	Cosentyx			S	Oral			Not Reported

	Abatacept	C	Subcutaneous		Not Reported
	Tocilizumab	C	Subcutaneous		Not Reported
	Leflunomide	C			Not Reported
	Leflunomide	C			Not Reported
	Leflunomide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17528689	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565797		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529132	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566099			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Methotrexate	S	Subcutaneous	Not Reported
	Minocycline	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529273	EXPEDITED (15-DAY)		DE	US-TEVA-2020-US-1196969		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Reconstitution Inflammatory Syndrome; Whipple'S Disease	Methylprednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Teva
	Celecoxib			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529304	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198615			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Gastric Disorder; Gastric Haemorrhage; Pain; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tylenol Arthritis Pain 8h			C				Not Reported

	Tylenol Arthritis Pain 8h			C	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529403	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1199756		60 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Influenza Like Illness; Pneumonia; Pneumonia; Pulmonary Fibrosis; Therapeutic Product Effect Incomplete; Tuberculin Test Positive	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529425	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1199839		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Ovarian Cancer; Rheumatoid Arthritis; Rheumatoid Nodule	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529432	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1199813		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Leukopenia; Memory Impairment; Mobility Decreased;	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

Nephrolithiasis; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529848	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1199821			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Nausea; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17529855	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1310			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17530810	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA067074		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis;	Neoral			S	Unknown	Unk		Novartis

Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Methotrexate		S	Unknown	Unk	Not Reported
	Celebrex		S	Unknown	Unk	Not Reported
	Cimzia		S	Subcutaneous	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Imuran		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17530886	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566092		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Insomnia; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Folic Acid			C				Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	M-Eslon			C	Unknown			Not Reported
	Morphine			C				Not Reported
	Morphine Sulfate			C	Unknown			Not Reported
	Venlafaxine Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17530896	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201901-000152			Unknown	CAN

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

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine	S	Unknown	Unk	Concordia
	Hydroxychloroquine	S	Unknown	Unk	Concordia
	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Concordia
	Hydroxychloroquine	S	Oral	200 Mg, Bid, Plaquenil	Concordia
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	Unk Unk, Qd	Not Reported
	Leflunomide	S	Unknown	10 Mg, Qd	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	40 Mg, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Arava	C		Unk	Not Reported
	Simponi	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17531084	EXPEDITED (15-DAY)		DS	CA-ROCHE-2563674		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Decreased; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17532826	NON-EXPEDITED			US-PFIZER INC-2020106873		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Cytotec			S		Unk		Pfizer
	Prevacid			S		Unk		Not Reported
	Cyclosporine			S		Unk		Not Reported
	Zelnorm			S		Unk		Not Reported
	Amitiza			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Reglan			S		Unk		Not Reported
	Maxzide			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17533105	EXPEDITED (15-DAY)		DS, OT	CA-SA-2018SA126625			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fear Of Injection; Joint Swelling; Loss Of Personal Independence In Daily	Plaquenil			S	Oral	Unk Unk,Unk		Sanofi
	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Celecoxib			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Oral	25 Mg,Qw		Not Reported
	Prednisone			S	Oral	5 Mg,Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Domperidone			C	Oral	10 Mg,Qd		Not Reported

Activities; Oedema Peripheral; Pain In Extremity; Rheumatoid Arthritis; Stress; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17533202	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020105885			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Herpes Zoster; Malaise; Pain; Rheumatoid Factor Increased; Therapeutic Response Decreased	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Arava			S				Not Reported
	Diclofenac			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Arthrotec			C				Not Reported
	Desoximetasone			C				Not Reported
	Ibuprofen			C				Not Reported
	Naproxen			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral			Not Reported
	Prednisone			C	Oral	Unk, 1x/Day		Not Reported
	Sulfasalazine			C				Not Reported
	Synthroid			C		Unk, 1x/Day		Not Reported
	Tramadol			C	Oral	Unk, 3x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17533357	EXPEDITED (15-DAY)		OT	NVSC2020CN068678		57 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Haemolytic Anaemia; Product Use In Unapproved Indication	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Mycophenolate Mofetil			S				Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported

	Tacrolimus	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17533406	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020101939		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Dilatation; Arthralgia; Drug Ineffective; Joint Swelling; Pulmonary Mass	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 3x/Day		Pfizer
	Hydroxychloroquine			S		700 Mg, 1x/Day		Not Reported
	Kevzara			S		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Vitamin D [Ergocalciferol]			C		Unk		Not Reported
	Candesartan			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17534005	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2020-CA-1198666		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure;	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Sepsis; Terminal State; Thrombosis	Humira	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Intravenous (not otherwise specified)	Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Ilaris Single-Use Vial	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17534213	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1200643			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Enbrel	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17534440	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1200638			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown	2.1429 Milligram Daily;		Barr
	Actemra			S	Unknown	18.9 Milligram Daily;		Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17534762	EXPEDITED (15-DAY)		OT	CA-PURDUE-CAN-2020-0010680		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Eye Disorder; Fatigue	Dilaudid			S	Unknown	Unk		Purdue
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Hydroxychloroquine	S	Unknown	Unk		Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Weekly		Not Reported
Prednisone	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17535515	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1199872			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	17535606	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1200575			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carpal Tunnel Syndrome; Drug Ineffective; Drug Ineffective; Fall; Fear Of Injection; Injection Site Warmth; Skin Reaction; Stress; Weight Increased; Wrist Fracture	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	11368759	NON-EXPEDITED		DE, HO, LT, OT	CA-AMGEN-CANSP2014104837		57 YR	Male	CAN

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

Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Enbrel	S	Subcutaneous	Unk	Amgen
	Enbrel	S	Unknown	Unk	Amgen
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported

Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Oxycodone	S	Unknown	10 Milligram	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Intra-arterial	Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Ilaris	S	Subcutaneous	Unk	Not Reported
Ilaris	S	Subcutaneous	Unk	Not Reported
Ilaris	S	Unknown	Unk	Not Reported
Ilaris	S	Unknown	Unk	Not Reported
Ilaris	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400 Mg, Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	Unk, Solution For Infusion	Not Reported
Xeljanz	S	Oral	Unk Unk, Bid	Not Reported
Xeljanz	S	Unknown	5 Milligram, Q2wk	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Oxyquinoline Sulfate	S	Unknown		Not Reported
Oxyquinoline Sulfate	S			Not Reported
Kineret	C		Unk	Not Reported
Lyrica	C	Oral	Unk	Not Reported

Rituximab W/Urelumab	C	Unknown	Unk		Not Reported
Prednisone	C		Unk Unk, Qd		Not Reported
Urelumab	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	11493051	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015093019		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Migraine; Neck Pain; Nodule; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12072431	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016015699		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Humira	S	Subcutaneous	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Gold	S	Unknown	Unk		Not Reported
Arava	S	Unknown	Unk		Not Reported
Plaquenil	S	Unknown	Unk		Not Reported
Apo Hydroxyquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12164789	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016118471		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	10 Mg, 2x/Day (Bid)		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Zostavax	S	Subcutaneous	Unk	Not Reported
Zostavax	S	Intravenous (not otherwise specified)	Unk	Not Reported
Zostavax	S	Unknown	Unk	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unk	Not Reported
Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Voltaren [Diclofenac]	C	Unknown	100 Mg, 1x/Day	Not Reported
Cortisone	C		10 Mg, Daily	Not Reported
Desoximetasone	C	Oral	10 Mg, 1x/Day	Not Reported
Desoximetasone	C		10 Milligram, Qd	Not Reported
Desoximetasone	C	Oral	5 Mg, 2x/Day	Not Reported
Desoximetasone	C	Subcutaneous	Unk	Not Reported
Diclofenac	C	Unknown	100 Mg, 1x/Day	Not Reported
Diclofenac	C	Oral	100 Mg, Unk	Not Reported
Diclofenac	C	Oral	5 Mg, 2x/Day	Not Reported
Diclofenac	C	Unknown	100 Mg, Unk	Not Reported

Diclofenac	C	Subcutaneous	100 Mg, Unk		Not Reported
Cortisone Acetate	C	Subcutaneous	Unk		Not Reported
Cortisone	C	Subcutaneous	Unk		Not Reported
Cortisone	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12224346	NON-EXPEDITED		OT	CA-AMGEN-CANSP2015029495		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	25 Milligram, Bid		Amgen
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen
	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Enbrel			S	Subcutaneous	25 Milligram		Amgen
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Methotrexate			S	Vaginal	25 Milligram, 4 Times/Wk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, 4 Times/Wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Unknown	200 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	200 Milligram, Bid		Not Reported

Humira	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qmo	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
Orencia	S	Unknown	Unk Unk, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	25 Milligram, Qwk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Unknown	40 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	4.0 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	40 Milligram	Not Reported
Arava	S	Unknown	20 Milligram, Qd	Not Reported
Arava	S	Unknown	20 Milligram	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Benadryl	C	Unknown	Unk Unk, As Necessary	Not Reported
Benadryl	C	Unknown	Unk	Not Reported

Synthroid	C	Unknown	Unk	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
Lasix	C		40 Milligram, Tid	Not Reported
Lasix	C	Unknown	Unk	Not Reported
Enablex	C	Unknown	Unk, As Necessary	Not Reported
Enablex	C	Unknown	Unk	Not Reported
Ativan	C	Unknown	1 Gram, Qd At Bedtime	Not Reported
Ativan	C	Unknown	Unk	Not Reported
Ativan	C	Unknown	1 Gram	Not Reported
Loperamide	C	Unknown	2 Milligram, Bid	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk Unk, Bid	Not Reported
Omnaris	C	Unknown	Unk	Not Reported
Pantoloc	C	Unknown	Unk	Not Reported
Vagifem	C	Vaginal	Unk	Not Reported
Vagifem	C	Unknown	Unk	Not Reported
Cortisone	C	Intra-arterial	Unk	Not Reported
Dilaudid	C	Unknown	4 Milligram, Qd	Not Reported
Dilaudid	C	Unknown	4 Milligram, Q6h	Not Reported
Dilaudid	C		4 Milligram	Not Reported
Dilaudid	C	Unknown	Unk	Not Reported
Abatacept	C		Unk	Not Reported
Leflunomide	C		Unk	Not Reported
Kineret	C		100 Milligram	Not Reported
Furosemide	C	Unknown	40 Milligram, Tid	Not Reported
Furosemide	C		40 Milligram, 3 Times/Wk	Not Reported
Furosemide	C	Unknown	Unk	Not Reported

Darifenacin Hydrobromide	C	Unknown	Unk Unk, As Required	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Unk Unk, As Necessary	Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Unk	Not Reported
Norflex	C	Unknown	Unk Unk, Bid	Not Reported
Norflex	C		Unk	Not Reported
Pantoprazole Sodium	C	Unknown	Unk	Not Reported
Anakinra	C	Unknown	100 Milligram	Not Reported
Anakinra	C	Unknown	100 Milligram	Not Reported
Desoximetasone	C	Oral	Unk	Not Reported
Desoximetasone	C	Intramuscular	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported
Kenalog	C	Intra-articular	40 Milligram	Not Reported
Kenalog	C	Unknown	40 Milligram	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported
Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	200 Milligram	Not Reported
Morphine Sulfate	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported
Dexamethasone	C	Oral	Unk	Not Reported
Darifenacin	C	Unknown	Unk	Not Reported
Dyclone	C	Unknown	Unk	Not Reported

Pantoprazole Sodium Anhydrous	C	Unknown	Unk		Not Reported
Plantago Ovata	C	Unknown	Unk		Not Reported
Dyclonine Hydrochloride	C		Unk		Not Reported
Orphenadrine	C	Unknown	1 Dosage Form, Bid		Not Reported
Pantoprazole	C	Unknown	Unk		Not Reported
Triamcinolone Acetonide	C	Intra-articular	40 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12298212	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2016050673		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness;	Enbrel			S	Unknown	25 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen
	Etanercept			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Etanercept			S	Unknown	50 Milligram, Qwk		Amgen
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	20 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported

Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Leflunomide	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
	Orencia	S	Unknown	780 Milligram, Qwk	Not Reported
	Orencia	S	Unknown	760 Milligram, Qwk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported

Rituxan	S	Unknown	1000 Milligram, Bid	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Actemra	S	Unknown	360 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	680 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	2.68 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	360 Milligram, Qmo	Not Reported
Actemra	S	Unknown	680 Milligram, Qmo	Not Reported
Actemra	S	Unknown	680 Milligram	Not Reported
Actemra	S	Unknown	360 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Q2wk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qwk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	20 Milligram	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram, Qmo	Not Reported
Tocilizumab	S	Unknown	680 Milligram, Q4wk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	15 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	17.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	12.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	12 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported

Methotrexate Sodium	S	Subcutaneous	70 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Oral	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Qd	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Milligram, Qmo	Not Reported
Simponi	S	Unknown	360 Milligram, Qmo	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Fosamax	S	Unknown	70 Milligram, Qwk	Not Reported
Alendronate	C	Unknown	70 Milligram, Qwk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported
Ciclosporin	C	Unknown	150 Milligram, Qd	Not Reported
Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Milligram, Q2h	Not Reported
Prednisone	C	Unknown	10 Milligram	Not Reported
Prednisone	C	Unknown	20 Milligram	Not Reported
Prednisolone	C		10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12650430	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016089419		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	11.2 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	1 Gram, Qd		Not Reported

Prednisone	C	Unknown	15 Milligram, Qd		Not Reported
Prednisone	C				Not Reported
Lyrica	C	Oral	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12682616	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016018624		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Increased; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Femur Fracture; Gait Disturbance; Gastric Disorder; Glycosylated Haemoglobin Increased; Heart Rate Increased; Hepatic Enzyme Increased; Infection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Nephrolithiasis; Neutrophil Count Increased; Off Label Use; Osteopenia; Pain; Pain In Extremity; Peripheral Swelling;	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	40 Milligram, Four Every One Week		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qd		Amgen
	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	50 Milligram, 4 Every 1 Week		Amgen
	Actemra			S	Intravenous (not otherwise specified)	800 Milligram, Q4wk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	Unk Unk, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported

Pyrexia; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence; Synovitis; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Orencia	S	Unknown	200 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Q4wk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Apo-Hydro	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Apo-Acetaminophen	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram, Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tylenol	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported

Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Acetaminophen	S	Unknown	325 Milligram	Not Reported
Acetaminophen	S	Oral	650 Milligram	Not Reported
Acetaminophen	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Amaryl	S	Unknown	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	Unk, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	Unk, Qwk	Not Reported
Methotrexate	S	Unknown	25 Dosage Form, Qwk	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Meloxicam	C	Unknown	Unk, Qwk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Tylenol With Codeine No.3	C		Unk	Not Reported
Celebrex	C	Oral	200 Milligram, Bid	Not Reported
Hydromorphone Hcl	C		Unk	Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported
Codeine	C	Unknown		Not Reported
Diphenhydramine	C	Oral	50 Milligram	Not Reported
Glyburide	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Lipitor	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk Unk, Qd	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported

	Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown	Unk		Not Reported
	Ramipril	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12691420	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016405201		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Xeljanz			S	Unknown	5 Milligram, Bid		Pfizer
	Minocycline			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	100 Milligram		Not Reported
	Azathioprine			S	Unknown	100 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Apo-Azathioprine			S	Unknown	100 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous drip	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Leflunomide	C	Unknown	Unk		Not Reported
Leflunomide	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12973995	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016163638		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	20 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Gold			S	Unknown	50 Milligram, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	8 Milligram		Not Reported
	Orencia			S	Unknown	750 Milligram, Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram		Not Reported
	Apo-Hydroxyquine			S	Unknown	20 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported

	Meloxicam		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	12982514	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016166769		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk (4 Years)		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported
	Coversyl			C	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Cephalexine			C	Unknown	500 Milligram, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	13814083	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017109326			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported

Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Rituxan	S	Unknown	1000 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Cortisone	C		10 Milligram, Qd	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Desoximetasone	C	Unknown	10 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	13857420	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2017119578		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Foot Operation; Ill-Defined Disorder; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	300 Milligram, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Cyclical	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	1.0 Dosage Form, Qd	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	Unk	Not Reported
Gold	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	300 Milligram, Qd	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Rituximab	S	Intravenous drip	1 Gram	Not Reported
Actonel	S	Unknown	35 Milligram, Qwk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	1.0 Dosage Form	Not Reported
Risedronate	S	Unknown	Unk	Not Reported
Risedronate	S	Unknown	35 Milligram, Qwk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	13859207	NON-EXPEDITED		HO	CA-AMGEN-CANSP2017119169			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported

Decreased; Viral Infection	Methotrexate	S	Oral	20 Milligram, Qwk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Apo-Folic Acid	S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine	S	Oral	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd		Not Reported
	Cymbalta	C	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	14551816	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018022286		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Hepatic Enzyme Increased; Liver Function Test Increased; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 Gram, Qd		Not Reported
	Xeljanz			C	Oral	5.0 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	14633220	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-003769		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Back Pain;	Orencia			S	Unknown	Unk		Bristol Myers Squibb

Condition Aggravated; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Humira	S	Subcutaneous	20 Mg, Qd	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram 4 Every 1 Week	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Milligram, Bid	Not Reported
	Winpred	S	Oral	5 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
	Prednisone	S	Oral	5 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Etanercept	S	Subcutaneous	50 Milligram	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	14680239	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018039685		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported

Actemra	S	Subcutaneous	162 Milligram, Qwk	Not Reported
Kevzara	S	Unknown	20 Mg, Unk (Every 14 Days For Eight Weeks)	Not Reported
Kevzara	S	Subcutaneous	20 Milligram, 1 Every 2 Weeks	Not Reported
Ciclosporin	S	Unknown	Unk	Not Reported
Esomeprazole Sodium	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	20 Milligram	Not Reported
Sarilumab	S	Subcutaneous	20 Milligram, Q2wk	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Nicotinamide	S	Unknown	Unk	Not Reported
Thiamine Hydrochloride	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Act Esomeprazole	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Adalimumab	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	400 Mg, Qd	Not Reported
Nexium	C	Unknown	Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Magnesium	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C		Unk	Not Reported
Dexpanthenol	C		Unk	Not Reported
Riboflavin	C		Unk	Not Reported
Vitamin A [Retinol]	C		Unk	Not Reported
Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
Esomeprazole	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	14767128	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018049251			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	15227464	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016244288			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	12.5 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Qd		Pfizer
	Methotrexate Sodium			S	Unknown	Unk 2 Year		Pfizer
	Methotrexate Sodium			S	Intramuscular	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Intramuscular	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	12.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	40 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	12.5 Mg, Qwk		Pfizer

Methotrexate Sodium	S	Intramuscular	12.5 Mg, Qd	Pfizer
Methotrexate Sodium	S	Unknown	12.5 Mg, Qwk	Pfizer
Methotrexate Sodium	S	Unknown	Unk Unk, 1 Every 2 Years	Pfizer
Methotrexate Sodium	S	Unknown	Unk	Pfizer
Arava	S	Oral	10 Mg, 2 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, 3 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, 1 Every 2 Days	Not Reported
Arava	S	Oral	10 Mg, Qd 3 Months	Not Reported
Arava	S	Oral	200 Mg, 2 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, Unk	Not Reported
Arava	S	Unknown	200 Mg, 2 Times/Wk	Not Reported
Arava	S	Oral	10 Mg, Q3wk	Not Reported
Arava	S	Unknown	10 Mg, 1x/Day	Not Reported
Arava	S	Oral	10 Mg, Bid	Not Reported
Arava	S	Oral	10 Mg, Q3mo	Not Reported
Arava	S	Unknown	200 Mg, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Plaquenil	S	Oral	200 Mg, Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Rituxan	S	Unknown	1000 Mg, Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Cyclical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported

	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	15552704	EXPEDITED (15-DAY)		OT	PHHY2018CA041941			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication; Rheumatoid Arthritis; Uveitis	Cosentyx			S	Unknown	Unk		Novartis
	Simponi			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Qd		Not Reported
	Plaquenil			S	Unknown	400 Mg		Not Reported
	Methotrexate			C	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	15620611	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2018-CA-975882			Female	CAN

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

Adrenal Insufficiency;	Methotrexate	S	Subcutaneous		Barr
Antibody Test Positive;	Methotrexate	S	Subcutaneous		Barr
Arthralgia; Arthritis;	Methotrexate	S	Unknown		Barr
Arthropathy; Body Height Below Normal; Bone	Methotrexate	S	Subcutaneous		Barr
Density Decreased; C-Reactive Protein	Methotrexate	S	Subcutaneous		Barr
Increased; Condition Aggravated;	Methotrexate	S	Intravenous (not otherwise specified)		Barr
Contraindicated Product Administered; Diarrhoea;	Methotrexate	S	Subcutaneous		Barr
Dizziness; Drug Ineffective; Drug	Naproxen	S	Unknown		Teva
Intolerance; Drug Specific Antibody; Drug Specific	Prednisone	S	Oral	10 Milligram Daily;	Actavis
Antibody Present; Gastroenteritis Viral;	Prednisone	S	Oral	2 Dosage Forms Daily;	Actavis
Gastroenteritis Viral; Human Anti-Human	Prednisone	S	Oral	6 Milligram Daily;	Actavis
Antibody Test; Human Antichimeric Antibody	Prednisone	S	Unknown	100 Milligram Daily;	Actavis
Positive; Hypocalcaemia; Hypokalaemia;	Prednisone	S	Unknown		Actavis
Hypotension; Immunodeficiency;	Prednisone	S	Unknown		Actavis
Immunodeficiency; Impaired Quality Of Life;	Prednisone	S	Oral	2.6 Milligram Daily;	Actavis
Joint Destruction; Joint Effusion; Joint Injury;	Prednisone	S	Oral	2.6 Milligram Daily;	Actavis
Juvenile Idiopathic Arthritis; Liver Function	Prednisone	S	Oral	6 Milligram Daily;	Actavis
Test Abnormal; Liver Function Test Abnormal;	Prednisone	S	Oral	6 Milligram Daily;	Actavis
Loss Of Consciousness; Loss Of Personal	Prednisone	S	Oral	10 Milligram Daily;	Actavis
Independence In Daily Activities; Mobility	Orencia	S	Intravenous (not otherwise specified)		Not Reported
Decreased; Nausea; Obesity; Off Label Use;	Orencia	S	Intravenous (not otherwise specified)		Not Reported
Pleural Effusion; Polyarthritis; Prescribed	Orencia	S	Intravenous (not otherwise specified)		Not Reported
Underdose; Product Use	Orencia	S	Intravenous (not		Not Reported

In Unapproved Indication; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Underdose; Vomiting; Wheelchair User			otherwise specified)		
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	250 Milligram Daily;	Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone	S	Other		Not Reported
	Triamcinolone	S	Intra-articular		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported

Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Subcutaneous		Not Reported
Infliximab	S	Unknown		Not Reported
Gamastan S/D Medicinal Ingredient Also Know As Immuneglobulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate Tablets, Usp	S	Oral	5 Mg/Kg Daily;	Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Subcutaneous	50 Milligram Daily;	Not Reported
Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Subcutaneous	50 Milligram Daily;	Not Reported
Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Subcutaneous		Not Reported
Kineret 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syri	S	Subcutaneous		Not Reported
Humira (Adalimumab)	S	Subcutaneous		Not Reported
Humira (Adalimumab)	S	Unknown		Not Reported
Prednisone	S	Oral	6 Milligram Daily;	Not Reported
Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported

Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)			Not Reported
Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)			Not Reported
Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)			Not Reported
Hydroxychloroquine	S	Oral	5 Milligram Daily;		Not Reported
Hydroxychloroquine	S				Not Reported
Hydroxychloroquine	S	Oral	5 Mg/Kg Daily;		Not Reported
Apo-Naproxen	S	Unknown			Not Reported
Apo-Naproxen	S	Oral	6 Milligram Daily;		Not Reported
Apo-Naproxen	S	Unknown			Not Reported
Anakinra	S	Subcutaneous	50 Milligram Daily;		Not Reported
Anakinra	S				Not Reported
Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)			Not Reported
Folic Acid	C	Unknown			Not Reported
Folic Acid	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	15702406	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016089441		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Orencia	S	Subcutaneous	125 Milligram, Qwk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	125 Milligram, Qwk	Not Reported
	Plaquenil	S	Oral	400 Milligram, Qd	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate	C	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate	C	Subcutaneous	17.5 Milligram	Not Reported
	Methotrexate	C	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	C	Unknown	17.5 Milligram	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	C	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate	C	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Sulfasalazine	C	Oral	1 Gram, Qd	Not Reported
	Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported
	Depo-Medrol	C		Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Tylenol 8 Hr Arthritis Pain	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	16439059	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2018011428		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram, 1x/Day		Not Reported
	Leflunomide			S	Unknown	10 Milligram, 1x/Day		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram 1 Every 6 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported

Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	200 Milligram	Not Reported
Methotrexate		S	Unknown	20 Milligram, Qwk	Not Reported
Aleve		C		Unk Unk, As Needed	Not Reported
Prednisone		C	Unknown	Unk	Not Reported
Arava		C	Unknown	Unk	Not Reported
Simponi		C	Subcutaneous	Unk	Not Reported
Simponi		C	Unknown	Unk	Not Reported
Xeljanz		C	Oral	5 Milligram	Not Reported
Xeljanz		C	Unknown	Unk	Not Reported
Bupropion		C		Unk	Not Reported
Sulfasalazine		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	16882113	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05704		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Etanercept			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported

Apo-Azathioprine	S	Unknown	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Unknown	Not Reported
Arava	S	Unknown	Unknown	Not Reported
Azathioprine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Leflunomide	S	Unknown	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Unknown	Not Reported
Methotrexate	S	Oral	Unknown	Not Reported
Methotrexate	S	Parenteral	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Methotrexate	S	Parenteral	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Unknown	Not Reported
Methotrexate	S	Other	Unknown	Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Actemra	S	Unknown	Unknown	Not Reported
Actemra	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Solution Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous	Not Reported
Xeljanz	S	Unknown	Unknown	Not Reported
Xeljanz	S	Oral		Not Reported
Tofacitinib	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17205119	EXPEDITED (15-DAY)		OT	CA-SA-2019SA353124		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Leflunomide			S		25 Mg, Qw		Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Arava			S		25 Mg, Qw		Sanofi
	Sulfasalazine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Actemra			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17390099	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200153298			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Hypersensitivity; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

	Otezla	S	Oral	Not Reported
	Otezla	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17448568	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007862		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17450389	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007813		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Apremilast			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

	Humira	S	Subcutaneous	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Otezla	S	Unknown	Unk		Not Reported
	Otezla	S	Oral	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Rituximab	S	Unknown	Unk		Not Reported
	Simponi	S	Unknown	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Infliximab	S	Unknown	Unk		Not Reported
	Infliximab	C	Unknown	Unk		Not Reported
	Penicillin /00000901/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535245	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567108		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535302	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566151		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug	Rituximab			S	Unknown			Not Reported

Ineffective; Osteoarthritis; Rheumatoid Factor Positive; Synovitis	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535341	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566061		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Haemorrhage	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Amlodipine Besilate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535494	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Rituximab			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535690	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201135			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral; Vision Blurred	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535822	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1201117			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Localised Infection; Malaise; Pleurisy; Pneumonia	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17535930	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1304		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Vomiting	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Gold Radioactive Colloidal			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)	
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536008	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201157			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Lower Respiratory Tract Infection; Neck Pain; Pain In Extremity; Peripheral Swelling	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536025	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201159		67 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Off	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine			S	Oral			Not Reported

Label Use; Product Use Issue; Somnolence	Sulfasalazine		S	Oral	2 Gram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536095	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201014		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536102	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201150			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cartilage Injury; Depression; Dizziness; Drug Ineffective; Grip Strength Decreased; Lethargy; Malaise; Nausea; Night Sweats; Palpitations; Panic Attack; Renal Function Test Abnormal; Tremor	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Diclofenac			C				Not Reported
	Diclofenac			C	Oral			Not Reported
	Diclofenac			C	Oral			Not Reported
	Diclofenac			C				Not Reported

	Sulfasalazine	C		2 Gram Daily;	Not Reported
	Tamsulosin Hydrochloride	C	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536155	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201165		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Rash; Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			C				Not Reported
	Actemra			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536157	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201155			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Neoral			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536347	EXPEDITED (15-DAY)		DS	CA-ROCHE-2567157		46 YR	Female	CAN

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

Disability; Mood Swings; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Treatment Failure	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Indometacin	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536389	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2020-012470		25 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Atorvastatin			S	Unknown	High Dose		Not Reported
	Clopidogrel			S	Unknown	Unk		Aurobindo
	Rivaroxaban			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Apixaban			S	Intracardiac	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536668	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020975			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536746	NON-EXPEDITED		OT	CA-AMGEN-CANSP2020039826		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased	Enbrel			S	Subcutaneous	Unk		Amgen

Arava	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536862	EXPEDITED (15-DAY)		OT	NVSC2020CA065750		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Neoral			S	Subcutaneous			Novartis
	Neoral			S	Oral	Unk		Novartis
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Cyclosporine			S	Unknown			Novartis
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Chloroquine			S	Subcutaneous			Not Reported

Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Unk		Not Reported
Apo-Leflunomide	S	Oral			Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
Orencia	S	Subcutaneous	125 Mg		Not Reported
Orencia	S	Subcutaneous	125 Mg		Not Reported
Plaquenil	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg		Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	S	Oral			Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Xeljanz Xr	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566115		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17536988	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003001464			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Musculoskeletal Stiffness; Pain	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17537638	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566129		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Fall; Off Label Use; Treatment Failure	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17537665	EXPEDITED (15-DAY)		OT	NVSC2020CA071564			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk, Bid (2 Every 1 Days)		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17537726	EXPEDITED (15-DAY)		OT	NVSC2020CN068677		49 YR	Female	CHN

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

Autoimmune Haemolytic Anaemia; Product Use In Unapproved Indication	Rituximab	S	Unknown	Unk		Not Reported
	Rituximab	S				Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk		Novartis
	Mycophenolate Mofetil	S				Novartis
	Cyclosporine	S	Unknown	Unk		Not Reported
	Cyclosporine	S				Not Reported
	Tacrolimus	S	Unknown	Unk		Not Reported
	Tacrolimus	S				Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17537962	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564643			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Atorvastatin Calcium			C	Unknown			Not Reported
	Pantoloc [Pantoprazole]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17539658	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201177			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17540077	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA067086		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Neoral			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk (Single-Use)		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported
	Imuran			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17540780	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201306		57 YR	Female	CAN

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

Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Upper Respiratory Tract Infection	Methotrexate	S	Unknown	25 Mg, 1 Every 1 Week	Barr
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Rituximab	S	Unknown		Not Reported
	Actemra	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Mar-2020	17541043	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201139			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rituxan			C	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

Anakinra	C	Unknown	Not Reported
Ativan	C	Unknown	Not Reported
Benadryl /00000402/	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Dexamethasone	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Dyclonine Hydrochloride	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported
Norflex /00018303/	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoloc /01263204/	C	Unknown	Not Reported
Pantoprazole Sodium	C	Unknown	Not Reported
Restasis	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	12507876	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016083007		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	100 Milligram, Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported
	Prednisone			C	Unknown	30 Milligram, Qd		Not Reported
	Cortisone			C		Unk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Methotrexate Sodium			C	Unknown	25 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	13436464	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016078528		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	125 Milligram, Qwk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	125 Milligram, Qwk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Gabapentin			C	Oral	400 Milligram, Tid 2 Tablets In The Mornings. 1 Tablet In The Aftenoon And 2 Tablets In The Evenings		Not Reported
	Gabapentin			C				Not Reported
	Xeljanz			C	Oral	5 Milligram, Qd		Not Reported
	Tylenol Arthritis			C	Unknown	650 Milligram, Qid		Not Reported

Acetaminophen	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	13913466	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017129066		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Oral	17.5 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	16968290	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2979286-00		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Arava	C		Not Reported
	Prednisone	C		Not Reported
	Aleve	C	Frequency-As Required	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	17433139	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2016091942		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Anxiety; Arthropathy; C-Reactive Protein; Chest Pain; Contraindicated Product Administered; Discomfort; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy;	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Milligram, Qd		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported

Musculoskeletal Pain; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Therapy Non-Responder; Treatment Failure; Urticaria; Wound	Atasol [Paracetamol]	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S			Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
	Sulfathalidine	S	Oral	500 Milligram	Not Reported
	Sulfathalidine	S	Oral	1000 Milligram, Bid	Not Reported
	Tofacitinib	S	Unknown	5 Milligram, Bid	Not Reported
	Tofacitinib Citrate	S	Unknown	5 Milligram, Bid	Not Reported
	Topicort [Hydrocortisone	S	Subcutaneous	Unk	Not Reported

Acetate]				
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S			Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram (1 Every 24 Hours)	Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Methotrexate	S	Unknown	25 Milligram (1 Every 24 Hours)	Not Reported
Methotrexate	S			Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S			Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Vitamin C	C		Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Glucosamine	C		Unk	Not Reported
Lansoprazole	C		30 Mg, Bid	Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	17541781	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565716			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported

Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Neoral	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Citalopram Hydrobromide	C	Unknown	Not Reported
	Citalopram Hydrobromide	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2020	17541831	EXPEDITED (15-DAY)		HO	CA-ROCHE-2566096			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2020	14400613	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2017193304		63 YR	Female	CAN

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

Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Enbrel	S	Subcutaneous	Unk	Amgen
	Enbrel	S	Subcutaneous	Unk	Amgen
	Pantoloc [Pantoprazole]	S	Unknown	40 Milligram, Qd	Not Reported
	Pantoloc [Pantoprazole]	S	Unknown	40 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Cyclical (Q2weeks)	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Cyclical (1/Week)	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Q2wk	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Q2wk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Bid	Not Reported
	Pantoprazole Sodium Anhydrous	S	Unknown	40 Milligram, Qd	Not Reported
	Pantoprazole Sodium Sesquihydrate	S	Unknown	40 Milligram, Qd	Not Reported
	Apo-Folic Acid	S	Unknown	5 Milligram, Bid	Not Reported
	Apo-Folic Acid	S	Unknown	5 Milligram, Bid	Not Reported
	Co Atenolol	S	Unknown	25 Milligram, Qd	Not Reported
	Co Atenolol	S	Unknown	20 Milligram, Qd	Not Reported
	Atenolol	S	Unknown	25 Milligram, Qd	Not Reported
	Naprosyn [Naproxen]	S	Oral	100 Milligram, Qd	Not Reported
	Naprosyn [Naproxen]	S	Oral	500 Milligram, Bid	Not Reported
	Naprosyn [Naproxen]	S	Oral	500 Milligram, Bid	Not Reported
	Naprosyn [Naproxen]	S	Oral	1000 Milligram, Qd	Not Reported
	Naproxen	S	Oral	100 Milligram, Qd	Not Reported
	Naproxen	S	Oral	500 Milligram, Qd	Not Reported

Palafer Cf	S	Unknown	Unk Unk, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
Pantoprazole Teva	S	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole Teva	S	Unknown	Unk	Not Reported
Ferrous Fumarate;Folic Acid	S	Unknown	Unk Unk, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Arava	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Humira	S	Subcutaneous		Not Reported
Orencia	S	Unknown	Unk, Qd	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Abatacept	S	Unknown		Not Reported
Ascorbic Acid	S	Unknown	Unk, Qd	Not Reported
Ascorbic Acid	S	Unknown	Unk, Qd	Not Reported
Ferrous Fumarate	S	Unknown	Unk	Not Reported
Ferrous Fumarate	S	Unknown	Unk, Qd	Not Reported
Folic Acid	S	Unknown	5 Milligram, Bid	Not Reported
Folic Acid	S	Unknown	5 Milligram, 2 Times/Wk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Qd	Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	40 Milligram	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Naproxen Sodium	S	Unknown	500 Milligram, Bid	Not Reported
	Naproxen Sodium	S	Unknown	1000 Milligram, Qd	Not Reported
	Naproxen Sodium	S	Unknown	500 Milligram, Bid	Not Reported
	Naproxen Sodium	S	Unknown	100 Milligram, Bid	Not Reported
	Naproxen Sodium	S	Unknown	1000 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qwk	Not Reported
	Hydroxychloroquine	S	Unknown	40 Milligram, Qwk	Not Reported
	Palafer	S	Unknown	Unk	Not Reported
	Pantoprazole Sodium	S	Unknown	40 Milligram, Qd	Not Reported
	Celebrex	C	Oral	200 Milligram, Qd	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Prednisone	C		5 Milligram, Qd	Not Reported
	Celecoxib	C	Oral		Not Reported
	Celecoxib	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2020	15620376	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556697-00		39 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported

Actemra	S	Unknown	Intravenous (Not Otherwise Specified)		Not Reported
Leflunomide	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Rituximab	S	Unknown	Intravenous (Not Otherwise Specified)		Not Reported
Plaquenil	S	Unknown			Not Reported
Hydroxychloroquine	C				Not Reported
Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2020	16867027	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2944310-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Bearing Difficulty	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2020	17542644	NON-EXPEDITED		HO	CA-AMGEN-CANSP2020042344		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Dysbiosis; Fatigue; Infection;	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen

Inflammation; Insomnia; Maternal Exposure During Pregnancy; Nausea; Pain; Psoriasis; Rheumatoid Factor Positive; Synovitis; Thyroid Disorder	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram	Not Reported
	Naproxen	S	Unknown	500 Milligram, Tid	Not Reported
	Naproxen	S	Unknown	500 Milligram, Tid	Not Reported
	Penicillin G [Benzylpenicillin]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C		Unk	Not Reported
	Synthroid	C		Unk	Not Reported
	Tramadol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	9459293	EXPEDITED (15-DAY)		OT	CA-ROCHE-1162770		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Diastolic Increased; Blood Pressure Increased; Blood Pressure Systolic Abnormal; Blood Pressure Systolic Increased; Cataract; Cystitis; Drug Intolerance; Dry Mouth; Dyslipidaemia; Fall; Hepatic Enzyme Increased; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Osteoporosis; Painful Respiration; Pharyngeal Mass; Pneumonia; Poor Venous Access; Synovitis; Upper Limb Fracture; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

	Synthroid	C			Not Reported
	Flexeril [Cyclobenzaprine Hydrochloride]	C			Not Reported
	Vitamin B Complex	C			Not Reported
	Tylenol	C			Not Reported
	Folic Acid	C			Not Reported
	Garlic [Allium Sativum]	C			Not Reported
	Methotrexate	C	Unknown		Not Reported
	Sulfasalazine	C	Oral		Not Reported
	Naprosyn [Naproxen]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	11350033	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-PFIZER INC-2015262877		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S				Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Methotrexate Sodium			S	Intra-arterial	Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Unk		Pfizer
	Sulfasalazine			S				Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Thrombosis; Urticaria	Plaquenil	S	Unknown	400 Mg, Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S			Not Reported
	Kineret	S		Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk, Single Use Vial	Not Reported
	Ilaris	S	Unknown	Unk, Single Use Vial	Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ilaris	S	Unknown	Unk (Powder For Injection)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S			Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
	Apo-Sulfasalazine	S		Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S			Not Reported

	Hydroxychloroquine	S			Not Reported
	Oxyquinoline Sulfate	S			Not Reported
	Oxyquinoline Sulfate	S			Not Reported
	Xeljanz	C	Oral	Unk Unk, Bid	Not Reported
	Xeljanz	C	Unknown	5 Milligram, Q2wk	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Rituximab W/Urelumab	C	Unknown	Unk	Not Reported
	Prednisone	C		Unk Unk, Qd	Not Reported
	Urelumab	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	11382867	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-PFIZER INC-2015267393		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Infliximab Hospira			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Pfizer
	Xeljanz			S	Unknown	5 Mg, Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Arava	C	Unknown	Unk		Not Reported
Arava	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12091497	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016085227		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Product Use Issue; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly (50 Milligram, Qwk)		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day (5 Milligram, Bid)		Pfizer
	Xeljanz			S		5 Ng, 2x/Day (5 Nanogram, Bid)		Pfizer
	Xeljanz			S		5 Mg, 2x/Day (5 Milligram,		Pfizer

			Bid)	
Sulfasalazine	S		Taken For 2 Years	Pfizer
Sulfasalazine	S	Oral	500 Mg, 1x/Day (500 Milligram, Qd)	Pfizer
Sulfasalazine	S	Unknown	Unk	Pfizer
Methotrexate Sodium	S	Subcutaneous	25 Mg, Unk (25 Milligram)	Pfizer
Methotrexate Sodium	S	Subcutaneous	25 Mg, Weekly (25 Milligram, Qwk)	Pfizer
Methotrexate Sodium	S	Subcutaneous	25 Mg, Unk (25 Milligram)	Pfizer
Methotrexate Sodium	S	Unknown	Unk	Pfizer
Plaquenil	S	Unknown	400 Mg, Taken For 2 Years	Not Reported
Plaquenil	S	Oral	200 Mg, 2x/Day (200 Milligram, Bid)	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S		40 Mg, 2x/Week (40 Milligram, Q2wk)	Not Reported
Humira	S		40 Mg, Unk (40 Milligram)	Not Reported
Humira	S	Subcutaneous	400 Mg, Unk (400 Milligram)	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Azathioprine	S		100 Mg, Unk (100 Milligram)	Not Reported
Apo-Azathioprine	S		Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	50 Mg, Unk (50 Milligram)	Not Reported

Minocycline Hydrochloride	S		Unk	Not Reported
Minocycline	S		Unk	Not Reported
Azathioprine	S	Unknown	100 Mg, Unk (100 Milligram)	Not Reported
Arava	S	Oral	20 Mg, Weekly (20 Milligram, Qwk)	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Mg, 1x/Day (20 Milligram, Qd)	Not Reported
Apo-Minocycline	S		50 Mg, Unk	Not Reported
Orencia	S		Unk, Monthly (Qmo)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Mg, Unk (400 Milligram)	Not Reported
Hydroxychloroquine Sulfate	S		400 Unk	Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Apo-Hydroxyquine	S		Unk	Not Reported
Leflunomide	C	Unknown	20 Unk, Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Amoxil	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Clavulin	C		Unk	Not Reported
Amoxicillin Trihydrate And Clavulanate Potass	C	Unknown	Unk	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk (Powder For Solution For Intravesical Use)	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk (Powder For Solution For Intravesical Use)	Not Reported
Bcg Vaccine	C	Unknown	Unk (Powder For Solution For Intravesical Use)	Not Reported
Adalimumab	C		Unk	Not Reported
Risedronate	C	Oral	35 Mg, Qwk	Not Reported

	Amoxicillin	C		Unk	Not Reported
	Amoxil [Amoxicillin Trihydrate]	C		Unk	Not Reported
	Hydroxychloroquine	C	Subcutaneous	400 Milligram	Not Reported
	Hydroxychloroquine	C	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine	C	Unknown	100 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12185482	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016145185		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis;	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	7.5 To 12.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	7.5 To 12.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk, Weekly		Pfizer
	Sulfasalazine			S	Oral	2.5 G, Daily		Pfizer
	Sulfasalazine			S	Oral	500 Mg, 1x/Day		Pfizer
	Gabapentin			S	Oral	100 Mg, 2x/Day		Pfizer
	Gabapentin			S	Unknown	100 Mg, 1 Every 2 Days		Pfizer
	Celebrex			S	Oral	Unk		Pfizer
	Celebrex			S		Unk, Occlusive Dressing Technique		Pfizer
	Fentanyl			S	Unknown	Unk		Pfizer
	Fentanyl			S	Unknown	Unk		Pfizer
	Celecoxib			S	Oral	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 1x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, Unk		Pfizer
	Plaquenil			S	Unknown	400 Mg, Daily (Qd)		Not Reported

Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Oxycontin	S	Unknown	Unk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Every 3 Weeks	Not Reported
	Myochrysine	S	Intramuscular	60 Mg, Cyclic Q3wk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported
	Orencia	S	Subcutaneous	Unk, Weekly	Not Reported
	Orencia	S	Vaginal	750 Mg, Monthly	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Cyclic Q3wk	Not Reported
	Orencia	S	Vaginal	750 Mg, Monthly	Not Reported
	Nortriptyline Hydrochloride/Perphenazine	S	Oral	10mg Tablets 1-3 Tablets Every Evening	Not Reported
	Nortriptyline Hydrochloride/Perphenazine	S	Oral	10 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Mg, Monthly	Not Reported
	Actemra	S	Oral	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	488 Mg, Cyclic Q4wk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Apo Fentanyl Matrix	S		Unk	Not Reported
	Apo Celecoxib	S	Oral	Unk	Not Reported
	Apo Gabapentin	S		Unk	Not Reported
	Apo Gabapentin	S	Oral	100 Mg, 2x/Day	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Fentanyl Matrix	S	Unknown	Unk Patch	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported

Omega-3 [Salmo Salar Oil]	S		Unk	Not Reported
Omega-3 Fatty Acids	C		1200 Mg, 2x/Day	Not Reported
Multivitamin	C		Unk	Not Reported
Tecta	C		40 Mg, Daily	Not Reported
Diphenoxylate	C		2.5/0.25 Milligram, Qd	Not Reported
Vitamin D	C		400 Iu, Daily	Not Reported
Vitamin D	C		400 Df, 1x/Day	Not Reported
Actonel	C		36 Mg, Weekly	Not Reported
Perphenazine	C	Oral	10 Mg, Unk	Not Reported
Prednisone	C	Unknown	5 Mg, Daily	Not Reported
Prednisone	C		Unk5.0 Gbq, Qd	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, (Every Four Weeks)	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Q2wk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C		Unk	Not Reported
Calcium	C		Unk	Not Reported
Fergon	C		300 Mg, Daily	Not Reported
Fergon	C		300 Mg, 1x/Day	Not Reported
Fergon	C		Unk	Not Reported
Tylenol	C	Oral	500 Mg 2 Tabs, 1x/Day	Not Reported
Tylenol	C	Oral	1000 Mg, 1x/Day	Not Reported
Nexium	C		40 Mg, 2x/Day	Not Reported
Trazodone Hcl	C	Oral	50 Mg, 1x/Day At Bedtime	Not Reported
Trazodone Hcl	C	Oral	50 Mg, 1x/Day	Not Reported
Nasonex	C	Nasal	2 Sprays, 2x/Day	Not Reported

Nasonex	C		Unk Unk, Bid (Spray Metered Dose)	Not Reported
Nasonex	C		2 Df, 2x/Day	Not Reported
Percocet	C		1 Tab 4-6h As Needed	Not Reported
Lomotil	C		2.5mg 3-4 Times/Day	Not Reported
Lomotil	C		2.5 Mg, Qd	Not Reported
Docosahexaenoic Acid	C	Unknown	Unk Unk, Qd	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Mg, 2x/Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, 1x/Day	Not Reported
Diphenoxylate Hydrochloride	C		Unk, 1x/Day	Not Reported
Diphenoxylate Hydrochloride	C		Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, 2x/Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Iu, 1x/Day	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C		Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C		1 Df, Unk	Not Reported
Trazodone	C		Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	40 Mg, 2x/Day	Not Reported
Esomeprazole	C		400 Mg, 2x/Day	Not Reported
Esomeprazole	C		Unk	Not Reported
Loperamide Hydrochloride	C		2.5 Mg, Unk	Not Reported
Ergocalciferol	C		400 Iu, 1x/Day	Not Reported
Ergocalciferol	C		Unk	Not Reported
Ergocalciferol	C	Unknown	Unk, 1x/Day	Not Reported
Tecta	C		40 Milligram, Qd	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Cyclic Qh	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Unk	Not Reported
Omega 3 2100	C		1200 Mg, 2x/Day	Not Reported

Omega 3 2100	C		Unk, Q2wk	Not Reported
Genteal [Hypromellose]	C		Unk	Not Reported
Fish Oil	C		1200 Mg, 2x/Day	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Ascorbic Acid	C		Unk	Not Reported
Biotin	C		Unk	Not Reported
Biotin	C		Unk	Not Reported
Nicotinamide	C		Unk	Not Reported
Pantoprazole	C		400 Mg, 1x/Day	Not Reported
Pantoprazole	C		40 Mg, 1x/Day	Not Reported
Pantoprazole	C		Unk	Not Reported
Pantoprazole	C		Unk	Not Reported
Pyridoxine Hydrochloride	C		Unk	Not Reported
Sodium	C		Unk	Not Reported
Thiamine Hydrochloride	C		Unk	Not Reported
Thiamine Hydrochloride	C		Unk	Not Reported
Vitamin A [Retinol]	C		Unk	Not Reported
Vit D3	C		Unk	Not Reported
Vitamin B12 [Cyanocobalamin]	C		Unk	Not Reported
Ferrous Fumarate	C		Unk	Not Reported
Ferrous Fumarate	C		Unk	Not Reported
Docosahexaenoic Acid/Eicosapentaenoic Acid	C		1200 Mg, 2x/Day	Not Reported
Docosahexaenoic Acid/Eicosapentaenoic Acid	C	Unknown	Unk Unk, Qd	Not Reported
Docosahexaenoic Acid/Eicosapentaenoic Acid	C	Unknown	Unk, Q2wk	Not Reported
Folic Acid	C		Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Retinol Palmitate	C		Unk	Not Reported
Retinol Palmitate	C		Unk	Not Reported

Riboflavin	C		Unk	Not Reported
Riboflavin	C		Unk	Not Reported
Sodium Ascorbate	C		Unk	Not Reported
Thiamine Mononitrate	C		Unk	Not Reported
Vitamine C	C		Unk	Not Reported
Vitamin D3	C		Unk	Not Reported
Loperamide	C		Unk	Not Reported
Perfenazine	C	Oral	10 Mg, Unk	Not Reported
Atropine Sulfate/Diphenoxylate Hydrochloride	C		Unk	Not Reported
Nortriptyline	C		Unk	Not Reported
Oxycodone And Acetaminophen	C		Unk	Not Reported
Epa Dha 720	C		Unk	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		Unk	Not Reported
Thiamine	C		Unk	Not Reported
Vitamin E [Tocopherol]	C		Unk	Not Reported
Cholecalciferol	C		Unk	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Qd	Not Reported
Vitamin B3	C		Unk	Not Reported
Vitamin B1 [Thiamine]	C		Unk	Not Reported
Vitamin B6	C		Unk	Not Reported
Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
Acetaminophen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12301979	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2014315082		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cardiovascular	Celebrex			S		200 Mg, 2x/Day (Bid)		Pfizer

Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Insomnia; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Enbrel	S	Subcutaneous	Unk	Pfizer
	Enbrel	S			Pfizer
	Methotrexate Sodium	S		Unk, Daily (Qd)	Pfizer
	Methotrexate Sodium	S			Pfizer
	Arava	S		Unk	Not Reported
	Arava	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk, Monthly	Not Reported
	Actemra	S			Not Reported
	Plaquenil	S		Unk	Not Reported
	Apo-Prednisone	S		14 Mg, 1x/Day	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk, 2x/Day	Not Reported
	Prednisone	S	Unknown	14 Mg, 1x/Day	Not Reported
	Dilaudid	C		4 Mg, 3x/Day	Not Reported
	Dilaudid	C			Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Furosemide	C		Unk, 1x/Day	Not Reported
	Hydromorph Contin	C		18 Mg, 3x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12302274	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016221150		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug	Enbrel			S	Unknown	25 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Pfizer
	Enbrel			S	Unknown	25 Mg, 2x/Week		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	25 Mg, Unk (1 Every 2 Week)		Pfizer

Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Enbrel	S	Unknown	50 Mg, Unk	Pfizer
	Etanercept	S	Unknown	25 Mg, 2x/Week	Pfizer
	Etanercept	S	Unknown	50 Mg, Weekly	Pfizer
	Celebrex	S		Unk	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Unknown	15.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Pfizer
	Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	17.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Q4wk	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	25 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	Unk	Pfizer
	Methotrexate Sodium	S	Oral	12.5 Mg, Unk	Pfizer

Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Oral	12.5 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Subcutaneous	10 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Subcutaneous	15 Mg, Unk	Pfizer
Methotrexate Sodium	S	Subcutaneous	70 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Pfizer
Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Pfizer
Methotrexate Sodium	S	Unknown	15.5 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Subcutaneous	10 Mg, Q4wk	Pfizer
Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q4wk	Pfizer
Methotrexate Sodium	S	Subcutaneous	12 Mg, Weekly	Pfizer
Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
Sulfasalazine	S	Unknown	Unk	Pfizer
Infliximab Hospira	S	Intravenous (not otherwise specified)	Unk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Mg, Monthly	Not Reported
Simponi	S	Unknown	360 Mg, Monthly	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Daily	Not Reported
Leflunomide	S		20 Mg, 5 Days Out Of 7	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Unk, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported

Humira	S	Subcutaneous	40 Mg, Every 2 Weeks	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 1x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Daily	Not Reported
Rituxan	S	Unknown	1000 Mg, 2x/Day	Not Reported
Actemra	S	Unknown	360 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, (Every 4 Weeks)	Not Reported
Actemra	S	Unknown	2.68 Mg, Q4wk	Not Reported
Actemra	S	Unknown	360 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, Unk	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	760 Mg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Alendronate	S	Unknown	Unk	Not Reported
Alendronate	S	Unknown	70 Mg, Weekly	Not Reported
Alendronate	S	Unknown	70 Mg, Weekly	Not Reported
Remicade	S	Intravenous (not	Unk	Not Reported

		otherwise specified)		
Myochrysine	S	Intramuscular	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
Myochrysine	S	Parenteral	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Cyclic (Once Every Two Weeks)	Not Reported
Myochrysine	S	Unknown	50 Mg, Monthly	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Tocilizumab	S	Unknown	380 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Week	Not Reported
Hydroxychloroquine	S	Oral	20 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	200 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Weekly	Not Reported
Rituximab	S	Unknown	1000 Mg, 2x/Day	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	70 Mg, Weekly	Not Reported
Alendronate Sodium	C	Unknown	Unk	Not Reported
Alendronate Sodium	C	Unknown	70 Mg, Weekly	Not Reported
Prednisone	C	Unknown	10 Mg, 1x/Day	Not Reported
Prednisone	C	Unknown	Unk	Not Reported

Prednisone	C	Unknown	10 Mg, (Every 2 Hours)		Not Reported
Prednisone	C		10 Mg, Unk		Not Reported
Prednisone	C	Unknown	10 Mg		Not Reported
Prednisone	C	Unknown	20 Mg, Unk		Not Reported
Cyclosporin	C	Unknown	150 Mg, 1x/Day		Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	5 Mg, 2x/Day		Not Reported
Prednisolone	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12338904	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016241427		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Rash; Skin Mass; Therapy Non-Responder	Enbrel			S	Subcutaneous	50 Mg, Once A Week		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Monthly		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer
	Tofacitinib Citrate			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid (2 Every 1 Day)		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	5 Mg, Bid		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Qd (1 Every 24 Hours)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Monthly		Not Reported
	Humira			S	Subcutaneous	40 Mg, Once Every Two Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Remicade	S	Subcutaneous	50 Mg, Weekly (1 Every 1 Week(S))	Not Reported
	Apo-Hydroxyquine	S	Oral	400 Mg, Qd (1 Every 24 Hours)	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Weekly	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Mg, Qd (1 Every 24 Hour)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12416801	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016278196		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis;	Enbrel			S	Unknown	50 Milligram		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram, Qd		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Infliximab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Actemra	S	Unknown	1 Dose	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Desoximetasone	S		Unk	Not Reported
	Humira	S		Unk	Not Reported
	Methadone	S		Unk	Not Reported
	Rampril	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Estrogel	C	Unknown	0.6 %, Three Times A Day	Not Reported
	Estrogel	C	Unknown	1.0 Df Qd	Not Reported
	Estradiol	C		Unk, Tid	Not Reported
	Calcium	C		500 Milligram, Qd	Not Reported
	Xalatan	C	Ophthalmic	50 Microgram, Qd (50 Mcg 0.005% 1 Drop)	Not Reported
	Cosopt	C		Unk, 2x/Day	Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
	Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
	Vitamin D	C		10000 Unit, Weekly	Not Reported
	Jampk20	C		1500 Mg, 1x/Day	Not Reported
	Zingiber Officinale	C	Oral	500 Mg, As Needed	Not Reported
	Dorzolamide Hcl And Timolol Maleate	C	Unknown	Unk, 2x/Day	Not Reported
	Ergocalciferol	C	Unknown	Unk, Weekly	Not Reported

	Ergocalciferol	C	Unknown	Unk, Qd	Not Reported
	Morphine	C	Unknown	Unk Unk, As Necessary	Not Reported
	Potassium Chloride	C	Unknown	1500 Mg, 1x/Day (Qd)	Not Reported
	Gravol Ginger	C	Oral	500 Milligram, As Needed	Not Reported
	Baclofen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12659993	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016335872		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	1 G, Qd		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	200 Mg, 2x/Day		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2x/Day		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	11.2 Milligram, Qd		Not Reported
	Plaquenil			S	Unknown	200 Mg, 2x/Day(Bid)		Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 2x/Day	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	1 Gram, Qd	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Prednisone	C	Unknown	15 Mg, Daily (Qd)	Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	12842578	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1958		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Inappropriate Schedule Of Product Administration; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Pantoloc			S	Unknown			Not Reported
	Pantoloc			S	Unknown			Not Reported
	Apo Folic Acid			S	Unknown	Twice In A Week		Not Reported
	Apo Folic Acid			S	Unknown	Twice A Week		Not Reported
	Naprosyn			S	Oral			Not Reported
	Naprosyn			S	Oral			Not Reported

Naprosyn	S	Oral		Not Reported
Naprosyn	S	Oral		Not Reported
Palafer Cf	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Abatacept	S	Unknown		Not Reported
Ascorbic Acid	S	Unknown		Not Reported
Ascorbic Acid	S	Unknown		Not Reported
Ferrous Fumarate	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown	2/Week	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown	Not Reported
Ferrous Fumarate-Folic Acid	S	Unknown	Not Reported
Pantoprazole Sodium Sesquihydrate	S	Unknown	Not Reported
Naproxen	S	Oral	Not Reported
Naproxen	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Atenolol	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Naproxen Sodium	S	Oral	Not Reported
Naproxen Sodium	S	Oral	Not Reported
Naproxen Sodium	S	Oral	Not Reported
Etanercept	S	Unknown	Not Reported
Palafer	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Pantoprazole Sodium	S	Unknown	Not Reported
Pantoprazole Sodium	S	Unknown	Not Reported
Pantoprazole Teva	S	Unknown	Not Reported
Pantoprazole Teva	S	Unknown	Not Reported
Ferrous Fumarate;Folic Acid	S	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Celecoxib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13033547	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-095488			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13128781	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017005116		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal	Enbrel			S	Unknown	25 Mg, 2 Times/Wk		Amgen
	Enbrel			S	Unknown	25 Mg, Unk		Amgen
	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	25 Mg, Bid		Amgen
	Arava			S	Unknown			Not Reported

Stiffness; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituximab	S	Unknown	1 Gram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	20 Mg, Qwk	Not Reported
	Methotrexate Sodium	S	Unknown	15 Mg, Qwk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Humira	S	Unknown	40 Mg, Cyclical	Not Reported
	Humira	S	Unknown	40 Mg, Q2wk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6wk	Not Reported
	Remicade	S	Unknown	300 Mg, Unk	Not Reported
	Remicade	S	Unknown	300 Mg, Cyclical	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Bid	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, Bid	Not Reported
	Apo-Hydroxyquine	S	Unknown	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	200 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Mg, Bid	Not Reported

Methotrexate	S	Unknown	20 Mg, Qwk		Not Reported
Methotrexate	S	Unknown	15 Mg, Qwk		Not Reported
Methotrexate	S	Unknown	20 Mg, Unk		Not Reported
Methotrexate	S	Unknown	200 Mg, Qwk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	1 G, Bid		Not Reported
Wellbutrin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13549390	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017071781		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	5 Mg, As Necessary		Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13761472	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017105360		66 YR	Female	CAN

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

Drug Ineffective; Rheumatoid Arthritis	Enbrel	S	Unknown	Unk	Amgen
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Celebrex	C		Unk, As Necessary	Not Reported
	Xeljanz	C		Unk	Not Reported
	Prednisone	C		Unk Unk, As Necessary	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13805299	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017112357		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Pressure Increased; Cataract; Cataract Operation; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Glaucoma Surgery; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Lyrica	C	Oral	Unk		Not Reported
Lyrica	C	Unknown	Unk		Not Reported
Prednisone	C	Oral	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Arava	C		Unk		Not Reported
Codeine	C	Unknown	Unk		Not Reported
Tylenol [Paracetamol]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13862390	NON-EXPEDITED		HO, OT	CA-AMGEN-CANSP2017119633		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; No Adverse Event; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Enbrel			S	Unknown	Unk		Amgen
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk, Qwk		Not Reported
	Naprosyn			C	Unknown	Unk		Not Reported

Erythromycin	C		Unk		Not Reported
Morphine	C	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13908900	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017128230		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Enbrel			S	Unknown	50 Milligram		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous drip	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Stelera			S	Subcutaneous	Unk		Not Reported

Stelera	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Myochrysine	S	Parenteral	Unk	Not Reported
Myochrysine	S	Intramuscular	Unk	Not Reported
Myochrysine	S	Subcutaneous	Unk	Not Reported
Myochrysine	S	Unknown	Unk	Not Reported
Otezla	S	Oral	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Sirukumab	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	S	Oral	5 Milligram, Bid	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Ustekinumab	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Minocin	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Salazopyrin	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	250 Milligram, Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported

Sulfasalazine	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	15 Milligram, Qwk		Not Reported
Methotrexate	S	Oral	Unk		Not Reported
Rheumatrex	C		Unk		Not Reported
Prednisone	C	Unknown	5 Milligram		Not Reported
Abatacept	C	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13909412	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017128000		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Dosage Form, Q2wk		Not Reported
	Orencia			S	Unknown	40 Milligram, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported

Leflunomide	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	2.5 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Folic Acid	C		2.5 Milligram, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Pantoprazol	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Oral	40 Milligram, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil [Tenofovir Disoproxil Fumarate]	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Zopiclone	C	Unknown	7.5 Milligram, Qd	Not Reported
Zopiclone	C	Unknown	Unk	Not Reported
Tenofovir	C		Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	300 Milligram, Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	300 Milligram, Unk	Not Reported
Pantoprazole Sodium	C	Unknown	Unk	Not Reported
Pantoprazole Bluefish	C	Unknown	Unk	Not Reported
Pantoprazole	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13909421	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017127635		67 YR	Female	CAN

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

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Enbrel	S	Unknown	Unk	Amgen
	Enbrel	S	Unknown	Unk	Amgen
	Enbrel	S	Unknown	Unk	Amgen
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk (Single Use Prefilled Syringe)	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Imuran	C	Unknown	Unk	Not Reported
	Arthrotec	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C		Unk	Not Reported
	Azathioprine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	13926256	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017375036		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Enbrel			S	Unknown	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	17.5 Mg, Qwk		Pfizer
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14156261	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017164983			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rash	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	1.0 Dosage Form, Qwk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Unknown	10 Milligram, Qd		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported

Methotrexate Sodium	S	Oral	Unk Unk, Qwk		Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid		Not Reported
Citalopram Hydrobromide	C	Unknown	40 Milligram, Qd		Not Reported
Citalopram Hydrobromide W/Mirtazapine	C	Unknown	40 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14185061	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170005		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Not Reported
	Folic Acid			C		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Restasis			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14186410	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170220			Female	CAN

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

Drug Ineffective; Rheumatoid Arthritis	Enbrel	S	Unknown	25 Milligram, Q2wk	Amgen
	Enbrel	S	Unknown	25 Milligram, Qwk	Amgen
	Enbrel	S	Unknown	25 Milligram	Amgen
	Enbrel	S	Unknown	25 Milligram, Cyclical	Amgen
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk (Solution Subcutaneous)	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk (Solution Subcutaneous)	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	20 Mg, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Mg, Qwk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil	S	Oral	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk, (Powder For Solution Intravenous)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Cyclical	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Qwk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk (Solution Intravenous)	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported
	Wellbutrin	C	Oral	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14190825	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017490362		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Inappropriate Schedule Of Product Administration; Injury; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Pfizer
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	200 Mg, Bid		Not Reported
	Folic Acid			C		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Restasis			C	Unknown	Unk (Emulsion)		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14216870	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017174939			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling;	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam	S	Oral	7.5 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Mobicox	S	Oral	7.5 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Sulfasalazine	C	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14217819	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017175088		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	10000 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14224287	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017175535		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14562748	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018073659		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Hepatic Enzyme Increased; Liver Function Test Increased; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	2 Gram, Qd		Pfizer
	Apo-Prednisone			S	Unknown	5 Milligram, Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd		Not Reported
Leflunomide	S	Oral	20 Milligram, Qd		Not Reported
Prednisone	S	Unknown			Not Reported
Xeljanz	C	Oral	5.0 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14623298	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018031822		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Treatment Failure; Uveitis	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	10 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Sarilumab	S	Unknown	Unk		Not Reported
Tofacitinib	S	Unknown	Unk		Not Reported
Adalimumab	S	Subcutaneous	40 Milligram		Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Qd		Not Reported
Prednisone	C		10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	14775658	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018157923			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15209356	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018101357			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Actemra			S	Subcutaneous	162 Mg, 2 Times/Wk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 3 Times/Wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported

	Hydroxychloroquine	S	Unknown	200 Mg, 2 Times/Wk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Unk, Unk (Three In One Week)	Not Reported
	Hydroxychloroquine	S	Unknown	200 Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Qwk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	20 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15286198	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016077975		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Rituximab			S	Intravenous drip	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15416427	EXPEDITED (15-DAY)		OT	PHHY2018CA102776		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Injection		Novartis
	Cyclosporine			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxyquinoline Sulfate			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported

Plaquenil	S	Oral	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Xeljanz	C	Unknown	2 Ot, Qd		Not Reported
Xeljanz	C	Oral	10 Mg, Qd		Not Reported
Xeljanz	C	Unknown	2 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15577112	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2541011-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Gait Disturbance; Multiple System Atrophy; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	579		Not Reported
	Xeljanz			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Xeljanz			C	Intravenous (not			Not Reported

					otherwise specified)					
	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15583667	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017372752		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	2.5 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	1 Df, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	10 Milligram, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	15 Milligram, Qwk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Dosage Form, Q2wk		Not Reported
	Orencia			S	Unknown	40 Milligram, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported

Folic Acid	C	Oral	2.5 Milligram, Qd		Not Reported
Folic Acid	C		Unk		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported
Pantoprazol	C	Unknown	Unk		Not Reported
Pantoprazole Magnesium	C	Oral	40 Milligram, Qd		Not Reported
Pantoprazole Magnesium	C	Unknown	Unk		Not Reported
Tenofovir Disoproxil [Tenofovir Disoproxil Fumarate]	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Zopiclone	C	Unknown	7.5 Mg, Daily		Not Reported
Zopiclone	C	Unknown	Unk		Not Reported
Tenofovir	C		Unk		Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	300 Milligram, Unk		Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Unk		Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	300 Milligram, Unk		Not Reported
Pantoprazole Sodium	C	Unknown	Unk		Not Reported
Pantoprazole Bluefish [Pantoprazole Sodium Sesquihydrate]	C	Unknown	Unk		Not Reported
Pantoprazole	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15585218	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-18K-028-2540122-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Disability; Drug Ineffective; Drug Ineffective; General Physical Health Deterioration; Infusion	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Gp2013		Not Reported

Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Rituximab	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S		Not Reported
	Abatacept	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15629800	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558453-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Inflammation; Joint Range Of Motion Decreased; Leg Amputation; Localised Infection; Osteoporosis; Peripheral Vascular	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Enbrel	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Acidophilus	C		Not Reported
	Aspirin	C		Not Reported
	Calcium	C		Not Reported
	Deflazacort	C		Not Reported
	Dilaudid	C		Not Reported
	Ergocalciferol	C		Not Reported
	Hydromorphone Hydrochloride	C	Intramuscular	Not Reported
	Januvia	C		Not Reported
	Kenalog	C	Intra-articular	Not Reported
	Lidocaine	C	Topical	Not Reported
	Metronidazole	C		Not Reported
	Nitroglycerin	C		Not Reported
	Pantoloc	C		Not Reported
	Pregabalin	C		Not Reported
	Pregabalin	C		Not Reported
	Pregabalin	C		Not Reported
	Risedronate	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Salbutamol	C		Not Reported
	Triamcinolone	C		Not Reported
	Tylenol	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Triamcinolone Acetonide	C		Not Reported
	Salicylic Acid	C		Not Reported
	Rosuvastatin	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15687047	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018170659		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Orencia			S	Oral	200 Milligram, Bid		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C		Unk		Not Reported
	Methotrexate			C	Oral	20 Milligram, Qwk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15700850	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018119653		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Enbrel			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Adalimumab			S	Unknown	Unk		Not Reported
	Act Esomeprazole			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported

Esomeprazole Sodium	S	Unknown	Unk		Not Reported
Folic Acid	S		Unk		Not Reported
Nicotinamide	S		Unk		Not Reported
Azathioprine	S		Unk		Not Reported
Thiamine Hydrochloride	S		Unk		Not Reported
Leflunomide	S	Oral	Unk		Not Reported
Gold	S	Unknown	Unk		Not Reported
Actemra	S	Subcutaneous	162 Mg, Qwk, Six Months		Not Reported
Kevzara	S		20 Mg, Unk (Every 14 Days For Eight Weeks)		Not Reported
Kevzara	S	Subcutaneous	20 Milligram, 1 Every 2 Weeks		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 1x/Day		Not Reported
Sarilumab	S	Subcutaneous	20 Mg, 2x/Week		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
Riboflavin	C		Unk		Not Reported
Vitamin A [Retinol]	C		Unk		Not Reported
Vitamin C [Ascorbic Acid]	C		Unk		Not Reported
Vitamin D [Ergocalciferol]	C	Unknown	Unk		Not Reported
Dexpanthenol	C		Unk		Not Reported
Esomeprazole Magnesium Trihydrate	C		Unk		Not Reported
Nexium [Esomeprazole Magnesium]	C	Unknown	Unk		Not Reported
Esomeprazole	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15704441	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018174077			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Headache;	Enbrel			S	Unknown	Unk		Amgen

Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Actemra	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Mg, Bid	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Kevzara	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminophen	C		650 Milligram, Bid	Not Reported
	Aluminium Acetate W/Benzethonium Chloride	C		Unk	Not Reported
	Atacand	C		Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Hydrodiuril	C	Unknown	Unk	Not Reported
	Neurontin	C	Unknown	600 Milligram, Tid	Not Reported
	Premarin	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	650 Mg, Bid	Not Reported
	Aluminium Acetate	C	Unknown	Unk	Not Reported
	Benzethonium Chloride	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	15924554	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653465-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported

Cimzia	S	Subcutaneous	Not Reported
Desoximetasone	S	Oral	Not Reported
Etanercept	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Reactine[Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16120373	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019045643		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

Methotrexate	S	Subcutaneous	25 Milligram, Qwk		Not Reported
Methotrexate	S	Oral	25 Milligram, Qd		Not Reported
Methotrexate	S	Oral	25 Milligram, Qwk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Unknown	Unk (Tablets)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
Sulfasalazine	S	Oral	500 Milligram, Qd		Not Reported
Arava	S	Oral	20 Milligram, Qd		Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd		Not Reported
Orencia	S	Unknown	75 Milligram, Qmo		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qwk		Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk		Not Reported
Gold	S	Unknown	Unk		Not Reported
Plaquenil S	C		Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Risedronate	C	Oral	35 Milligram, Qwk		Not Reported
Cimzia	C	Subcutaneous	200 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16140862	EXPEDITED (15-DAY)		OT	CA-SA-2019SA083231		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Enbrel			S		50 Mg		Not Reported
	Orencia			S				Not Reported

Rituxan	S	Solution Intra Venous		Not Reported
Salazopyrin	S			Not Reported
Actemra	C			Not Reported
Bifidumbacterin	C			Not Reported
Celebrex	C			Not Reported
Loperamide	C			Not Reported
Methotrexate	C			Not Reported
Pantoprazole	C			Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16181416	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2738191-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Pneumocystis Jirovecii Pneumonia; Pulmonary Fibrosis; Synovitis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16291815	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-087638			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug	Aleve			S	Unknown	Unk		Bayer
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Kineret			S	Subcutaneous	50.0 Mg, Qd		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Oral	5.0 Mg, Bid		Not Reported
	Enbrel			S	Subcutaneous	25.0 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, 4iw		Not Reported

Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous	25 Unk	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	70.0 G	Not Reported
	Hydroxychloroquine	S	Oral	5.0 Mg, Qd	Not Reported
	Infliximab	S	Unknown	5.0 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3.0 Mg, Ow	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Mg, Ow	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250.0 Mg, Q1mon	Not Reported
	Prednisone	S	Oral	3.0 Mg, Bid	Not Reported
	Prednisone	S	Oral	5.0 Unk	Not Reported
	Sulfasalazine	S	Oral	250.0 Mg, Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280.0 Mg, Q2wk	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Ow	Not Reported
	Triamcinolone	S	Subcutaneous	25.0 Mg, Q2wk	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unk	Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Gamastan	S		70.0 G	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5.0 Mg/Kg, Qd	Not Reported
	Naproxen	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Immunoglobulin I.V	S	Intravenous (not otherwise specified)	70.0 G	Not Reported
	Triamcinolone Hexacetonide	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16330442	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019077665			Female	CAN

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

Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Enbrel		S	Unknown	Unk	Amgen
	Actemra		S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	20 Milligram, Qd	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Methotrexate		S	Unknown	20 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	400 Milligram, Qd	Not Reported
	Sulfasalazine		S	Unknown	2 Gram, Qd	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram, Qd	Not Reported
	Xeljanz		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16470848	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2018036164		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S	Unknown	25 Milligram, Q2wk		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	15 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	10 Milligram, 1x/Day		Not Reported
	Leflunomide			S	Unknown	10 Milligram, 1x/Day		Not Reported

Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram 1 Every 6 Weeks	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram	Not Reported
Aleve	C		Unk Unk, As Needed	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported
Simponi	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Bupropion	C		Unk	Not Reported
Sulfasalazine	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16471566	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017312936		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	25 Mg, 2x/Week		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S	Oral	Unk		Not Reported
	Remicade			S	Unknown	300 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	1000 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Gold			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Desoximetasone			C	Unknown	10 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16483146	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2017349309		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported

Use; Rheumatoid Arthritis	Anakinra	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	1.0 Dosage Form, Qd	Not Reported
	Hydroxychloroquine	S	Oral	300 Mg, 1x/Day	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Cyclic	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Oral	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, 1 Every 1 Hour(S)	Not Reported
	Leflunomide	S	Unknown	1.0 Dosage Form	Not Reported
	Leflunomide	S	Oral	20 Mg, 1x/Day	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	300 Mg, 1x/Day	Not Reported
	Actonel	S	Unknown	35.0 Mg, Weekly	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Risedronate	S	Unknown	Unk	Not Reported
	Risedronate	S		35 Mg, Weekly	Not Reported
	Methotrexate	C		Unk	Not Reported

	Xeljanz		C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16628388	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2863507-00		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16793789	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018056893		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	50 Milligram, Qd		Amgen
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Neoral			S	Unknown	Unk		Not Reported
	Neoral			S	Oral	Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported

	Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16797341	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019146895		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel			S	Unknown	50 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Ergocalciferol			C		Unk Unk, Qwk		Not Reported

	Dorzolamide Hydrochloride And Timolol Maleate	C	Unknown	Unk Unk, Bid	Not Reported
	Estrogel	C		0.6 Percent, Tid	Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Potassium Chloride	C	Unknown	1500 Milligram, Qd	Not Reported
	Valsartan	C		320 Milligram, Qd	Not Reported
	Xalatan	C		50 Microgram, Qd	Not Reported
	Zingiber Officinale	C	Oral	500 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16807532	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019147890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	750 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Gold			S	Unknown	50 Milligram		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16848358	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019155529			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	16948402	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2972424-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspnoea; Leukoplakia Oral; Lung Disorder; Pneumonia; Pyrexia	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17036954	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019493883		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Asthma; Atelectasis; Blood Disorder; Blood Immunoglobulin E Increased; Bronchial Wall Thickening; Bronchiolitis; Condition Aggravated; Cough; Dysphonia; Dyspnoea; Eosinophil Count Increased; Eosinophilic Granulomatosis With Polyangiitis; Fungal Infection; Infection Parasitic; Inflammation; Malaise; Oropharyngeal Pain; Pneumonia; Pneumonitis; Productive Cough; Secretion Discharge; Sinusitis; Skin Disorder; Sleep Disorder Due To A General Medical Condition; Spirometry Abnormal; Suprapubic Pain; Systemic Inflammatory Response Syndrome; Therapeutic Product Effect Incomplete; Underweight; Vasculitis; Weight Decreased; Wheezing	Pantoloc			S	Unknown	40 Milligram		Pfizer
	Omnaris			S	Unknown	50 Microgram		Not Reported
	Alvesco			S	Unknown	200 Microgram, Qd		Not Reported
	Ivermectin			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	5 Milligram		Not Reported
	Prednisone			S	Oral	50 Milligram		Not Reported
	Salbutamol Sulfate			S	Unknown	100 Microgram		Not Reported
	Umeclidinium Bromide			S	Unknown	62.5 Microgram		Not Reported
	Zenhale			S	Unknown	2 Df, Bid		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17038283	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1116759		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis; Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Hepatic Congestion; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis;	Furosemide			S	Unknown			Ivax
	Mycophenolate Mofetil			S	Unknown	1000 Milligram Daily;		Teva
	Mycophenolate Mofetil			S	Unknown	1000 Milligram Daily;		Teva
	Piperacillin Sodium /Tazobactam Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
	Prednisone			S	Unknown			Actavis
	Rosuvastatin Calcium			S	Unknown			Teva
	Vancomycin Hydrochloride			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram Daily;		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram Daily;		Not Reported
	Ceftazidime			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Actonel			C				Not Reported
	Apo Amlo			C				Not Reported
	Apo-K			C				Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported
	Epoetin Alfa			C				Not Reported
	Escitalopram			C	Unknown			Not Reported
	Hydrochlorothiazide			C				Not Reported
	Ventolin [Salbutamol Sulfate]			C				Not Reported
	Tylenol [Paracetamol]			C				Not Reported
	Slow-K			C				Not Reported
	Risedronate			C				Not Reported
	Pantoprazole			C				Not Reported
	Pantoloc [Pantoprazole]			C		40 Milligram Daily;		Not Reported
	Metoprolol			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Metformin			C				Not Reported

Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Kcl	C	Not Reported
	Januvia	C	Not Reported
	Insulin Lispro	C	Not Reported
	Hydroxychloroquine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17205986	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA353135		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Sodium Aurothiomalate			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Arava			S	Oral	10 Mg		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Leflunomide			S		10 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		300 Mg		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Methotrexate			S		12.5 Df		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Plaquenil			S				Sanofi
	Sulfasalazine			S				Not Reported
	Actemra			S		Unk		Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Subcutaneous	25 Mg		Not Reported

	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous	250 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6w	Not Reported
	Rituximab	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Bifidobacterium Bifidum	C			Not Reported
	Celebrex	C			Not Reported
	Loperamide	C			Not Reported
	Pantoprazole	C			Not Reported
	Prednisone	C		40 Mg	Not Reported
	Prednisone	C		250 Unk	Not Reported
	Simponi	C			Not Reported
	Sulfasalazine	C			Not Reported
	Wellbutrin	C			Not Reported
	Xeljanz	C	Oral	5 Mg	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C		200 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17211808	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA354607			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis;	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Methotrexate			S		25 Mg, Qw		Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Plaquenil			S		200 Mg		Sanofi
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Mg Bid		Not Reported

Sleep Disorder Due To General Medical Condition, Insomnia Type	Prednisone	S		20 Mg, Qd	Not Reported
	Prednisone	S		20 Mg, Qd	Not Reported
	Arava	S		10 Mg, Qd	Sanofi
	Sodium Aurothiomalate	S		Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Bim	Not Reported
	Actemra	S			Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Orencia	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2 G, Q6m	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17215414	EXPEDITED (15-DAY)		OT	CA-SA-2019SA353952		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Sodium Aurothiomalate			S		Unk		Not Reported
	Sodium Aurothiomalate			S		Unk/Gold		Not Reported
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Orencia	S	Subcutaneous	125 Mg, Qw		Not Reported
Orencia	S	Intravenous (not otherwise specified)	125 Mg, Qw		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported
Depo-Medrol	C		Unk		Not Reported
Methotrexate	C	Subcutaneous	15 Mg, Qw		Not Reported
Methotrexate	C	Unknown	15 Mg, Qw		Not Reported
Methotrexate	C	Subcutaneous	17.5 Mg		Not Reported
Methotrexate	C	Unknown	17.5 Mg		Not Reported
Methotrexate	C	Subcutaneous	25 Mg, Qw		Not Reported
Methotrexate	C	Subcutaneous	20 Mg, Qw		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Oral	1 G, Qd		Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17427584	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1186381		11 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cryptosporidiosis Infection; Hypogammaglobulinaemia; Leukopenia; Neutropenia; Weight Decreased	Hydroxychloroquine			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17434479	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019415671			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17449016	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007838		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Finger Deformity; Foot Deformity; Gastrointestinal Disorder; Loss Of Personal Independence In Daily Activities; Nausea	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Methotrexate			S	Parenteral	15 Mg, Unk		Not Reported
	Methotrexate			S	Parenteral	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17449345	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007801			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Aleve			C	Unknown	Unk		Not Reported
	Enbrel			C	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Sulfasalazine			C	Oral	2000 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17454345	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007815		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lymphoma	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Desoximetasone			C	Unknown	10 Mg, Qd		Not Reported
	Diclofenac			C	Unknown	100 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17482799	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008186		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; C-Reactive Protein; Drug Intolerance; Fatigue; Finger Deformity; Gastrointestinal Disorder; Hypersensitivity; Nausea; Pain; Paraesthesia; Rheumatoid Arthritis; Swelling; Swollen Joint Count; Therapeutic Product Effect Incomplete; Urticaria	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Enbrel			S	Unknown	Unk, Unknown		Not Reported
	Methotrexate			S	Unknown	Unk, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Sarilumab			C	Unknown	Unk, Unknown		Not Reported
	Xeljanz			C	Unknown	Unk, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17485926	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008204			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17542948	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566947			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17542960	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566909		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Dequalinium Chloride	C		Not Reported
	Mefenamic Acid	C		Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Tylenol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543158	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022567		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Sulfasalazine		C	Unknown	1 Gram, Bid	Not Reported
	Wellbutrin		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543200	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022609			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543230	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566985			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543233	EXPEDITED (15-DAY)		DE, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1339		70 YR	Male	CAN

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

Blister; Chills; Erythema; Fatigue; Hypotension; Klebsiella Infection; Leukopenia; Multiple Organ Dysfunction Syndrome; Odynophagia; Product Use Issue; Rash; Rash Vesicular; Skin Lesion; Thrombocytopenia; Varicella Zoster Virus Infection	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543235	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1364		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543244	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1369			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Increased; Herpes Zoster; Ill-Defined Disorder; Malaise; Pain; Rheumatoid Factor Increased; Therapeutic Response Decreased	Diclofenac	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Ibuprofen	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543246	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1323		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aortic Dilatation; Arthralgia; Drug Ineffective; Joint Swelling; Pulmonary Mass	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Vitamin D			C	Unknown			Not Reported
	Candesartan			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543431	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567727			Female	CAN

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

Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Minocycline	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium	C	Unknown	Not Reported
	Amoxil [Amoxicillin]	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543593	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201880			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Fatigue; Feeling Abnormal; Therapeutic Response Decreased	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543644	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022646			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Drug	Orencia			S	Unknown			Bristol Myers Squibb

Ineffective; Joint Swelling	Adalimumab	S	Subcutaneous			Not Reported
	Azathioprine	S	Unknown			Not Reported
	Gold	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Rituximab	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Amitriptyline	C	Unknown			Not Reported
	Cefazolin	C	Unknown			Not Reported
	Clindamycin	C	Unknown			Not Reported
	Prednisone	C	Unknown	10 Milligram		Not Reported
	Tylenol W/Codeine No. 3	C	Unknown			Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543729	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1202304		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Off Label Use; Pharyngeal Oedema; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Arava			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543733	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1202183		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543737	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1202308		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate			S	Subcutaneous	3.5714 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	2.1429 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543813	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1202024			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Methotrexate			S	Unknown			Barr
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Actavis
	Diclofenac Potassium			S	Unknown			Actavis
	Sulfamethoxazole W/Trimethoprim			S	Unknown			Teva
	Sulfamethoxazole W/Trimethoprim			S	Unknown			Teva
	Apo-Diclofenac			S	Topical			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Gold Sodium Thiomalate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Voltaren			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17543832	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201901			Female	CAN

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

Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis; Synovitis	Methotrexate	S	Unknown	Barr
	Humira	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544307	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020899		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amyotrophic Lateral Sclerosis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Q4wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544337	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567702		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544346	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544394	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567710		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported

Arthritis; Stomatitis	Doxycycline		S	Unknown	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Methotrexate		S	Oral	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Prednisone		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Prednisone		C	Unknown	Not Reported
	Tylenol 8 Hr Arthritis Pain		C	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544665	NON-EXPEDITED			US-PFIZER INC-2020112039		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544958	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-MYLANLABS-2020M1026331		31 YR	Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy;	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Omeprazole			S	Unknown	Unk		Unknown

Oligohydramnios; Premature Baby	Cefotaxime	S	Unknown	Unk	Mylan
	Cefotaxime	S		Unk	Mylan
	Privigen	S	Unknown	Unk	Mylan
	Privigen	S		Unk	Mylan
	Prednisone	S	Unknown	Unk	Mylan
	Methylprednisolone	S	Unknown	Unk	Mylan
	Dexamethasone	S		Unk	Mylan
	Dexamethasone	S	Unknown	Unk	Mylan
	Vitamin B Complex /04259401/	S	Unknown	Unk	Mylan
	Cefixime	S	Unknown	Unk	Mylan
	Metoprolol Tartrate	S	Unknown	Unk	Mylan
	Bisoprolol Fumarate	S	Unknown	Unk	Mylan
	Penicillin G /00000903/	S	Unknown	Unk	Mylan
	Vulmizolin	S	Unknown	Unk	Mylan
	Bisulepin	S	Unknown	Unk	Mylan
	Ornidazole	S	Unknown	Unk	Mylan
	Albumin	S	Unknown	Unk	Mylan
	Aminomethylbenzoic Acid	S	Unknown	Unk	Mylan
	Magnesium Lactate	S	Unknown	Unk	Mylan
	Folic Acid	S	Unknown	Unk	Mylan
	Nadroparin Calcium	S	Unknown	Unk	Mylan
	Hydroxychloroquine	S	Unknown	Unk	Mylan
	Vitamin D /00318501/	S	Unknown	Unk	Mylan
	Hydrocortisone	S	Unknown	Unk	Mylan
	Etamsylate	S	Unknown	Unk	Mylan
	Flebogamma Dif /00025201/	S	Unknown	Unk	Mylan
	Fluconazole	S	Unknown	Unk	Mylan
	Potassium Chloride	S	Unknown	Unk	Mylan
	Paracetamol	S	Unknown	Unk	Mylan

	Vitamin K Nos		S	Unknown	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544990	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166761		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Adverse Drug Reaction; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Joint Swelling; Joint Swelling; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Toxicity To Various Agents; Visual Impairment; Visual Impairment	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Orencia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	125 Mg, Qw		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Adalimumab			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			C	Subcutaneous	17.5 Mg,Unk		Not Reported
	Methotrexate			C	Subcutaneous	15 Mg,Qw		Not Reported
	Methotrexate			C	Unknown	17 Mg		Not Reported
	Methotrexate			C	Unknown	15 Mg, Qw		Not Reported

Methotrexate	C	Subcutaneous	25 Mg, Qw		Not Reported
Methotrexate	C	Subcutaneous	20 Mg, Qw		Not Reported
Sulfasalazine	C	Oral	1 G,Qd		Not Reported
Xeljanz	C	Oral	5 Mg,Bid		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported
Depo-Medrol	C		Unk		Not Reported
Prednisone	C		Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17544993	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA210576		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Arava			S	Oral	10 Mg,Unk		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Leflunomide			S		10 Mg Qd		Sanofi
	Leflunomide			S		Unk		Sanofi
	Sodium Aurothiomalate			S	Intramuscular	Unk Unk,Unk		Not Reported
	Sodium Aurothiomalate			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S		Unk Unk,Unk		Sanofi
	Methotrexate			S		20 Mg, Qw, Solution		Not Reported
	Methotrexate			S	Unknown	12.5 Df,Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S		300 Mg		Sanofi
	Humira			S	Subcutaneous	40 Mg,Qow		Not Reported
	Orencia			S	Subcutaneous	25 Mg		Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	250 Mg	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Unk	Not Reported
	Rituxan	S		Unk	Not Reported
	Gold	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	25 Mg	Not Reported
	Enbrel	S		50 Mg	Not Reported
	Actemra	S			Not Reported
	Actemra	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6w	Not Reported
	Prednisone	C	Unknown	40 Mg, For 3 Years	Not Reported
	Prednisone	C	Unknown	250 Mg, For 7 Months	Not Reported
	Bifidobacterium Bifidum	C			Not Reported
	Celebrex	C			Not Reported
	Loperamide	C			Not Reported
	Sulfasalazine	C			Not Reported
	Pantoprazole	C			Not Reported
	Xeljanz	C	Oral	5 Mg	Not Reported
	Simponi	C			Not Reported
	Wellbutrin	C			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Oral	200 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17545125	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2020M1026414			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anaemia; Arthralgia; Fall; Lower Limb Fracture; Occult Blood Positive; Osteoarthritis; Pruritus;	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Unk		Not Reported

Urinary Tract Infection	Methotrexate	S	Unknown	5 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	2.5 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	7.5 Mg, Unk	Not Reported
	Mabthera	S	Unknown	500 Mg, Unk	Mylan
	Mabthera	S	Unknown	500 Mg, Unk	Mylan
	Mabthera	S	Unknown	500 Mg, Unk	Mylan
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Mylan
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Mylan
	Rituximab	S	Unknown	500 Mg, Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17545370	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020112214			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown			Pfizer
	Xeljanz			S	Unknown			Pfizer
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17545594	EXPEDITED (15-DAY)		OT	CA-SA-2019SA130822		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Headache; Joint Swelling; Pain In Jaw; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg		Sanofi
	Arava			S		Unk		Sanofi
	Meloxicam			S		15 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Atorvastatin Calcium			C		20 Mg		Not Reported

	Symbicort	C	Unk		Not Reported
	Gabapentin	C	100 Mg		Not Reported
	Lansoprazole	C	30 Mg		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546119	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1198500			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Haemorrhage	Hydroxychloroquine Sulfate Teva			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546196	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020111601		48 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombophlebitis Superficial	Torvast			S				Pfizer
	Paracetamol Alter			S	Oral	1 G, 1x/Day		Not Reported
	Xarelto			S	Oral	20 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546249	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA069998		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis;	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported

Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Oxycodone	S	Unknown	10 Mg	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S			Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S			Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Minocycline	S			Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S			Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Cannabis Sativa	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S			Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported

	Sulfasalazine	S	Unknown	500 Mg		Not Reported
	Sulfasalazine	S				Not Reported
	Xeljanz	S	Oral	2 Df, Qd		Not Reported
	Rituximab	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546340	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3318751-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo Azathioprine			S	Unknown			Not Reported
	Apo Leflunomide			S	Oral			Not Reported
	Apo Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Celecoxib			S	Unknown			Not Reported
	Celecoxib			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Acetaminophen	C		Not Reported
Codeine Phosphate	C		Not Reported
Altace	C		Not Reported
Apo Gabapentin	C	Oral	Not Reported
Atorvastatin Calcium	C		Not Reported
Escitalopram	C		Not Reported
Citalopram Hydrobromide	C		Not Reported
Conjugated Estrogens	C		Not Reported
Cymbalta	C		Not Reported
Escitalopram	C		Not Reported
Estrace	C		Not Reported
Gabapentin	C		Not Reported
Hydrochlorothiazide	C		Not Reported
Hydromorphone Hcl	C		Not Reported
Mupirocin	C	Topical	Not Reported
Pantoprazole	C		Not Reported
Shark Liver Oil	C		Not Reported
Tapentadol Hydrochloride	C		Not Reported
Taro Mupirocin	C	Topical	Not Reported
Tramacet	C	Oral	Not Reported
Tramadol Hydrochloride	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546508	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021288		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported

Arava	S	Oral	20 Milligram, Qd		Not Reported
Arava	S	Oral	Unk		Not Reported
Cimzia	S	Subcutaneous	Unk		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid		Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546844	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1202539		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Condition Aggravated; Diverticulitis; H1n1 Influenza; Hepatic Enzyme Increased; Hepatomegaly; Palpitations; Pneumonia; Renal Disorder; Tooth Extraction; Tooth Infection	Methotrexate			S	Unknown			Barr
	Chloroquine Diphosphate			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546910	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1202524		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Intramuscular			Barr
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

	Arava	S	Oral	10 Milligram Daily;	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Asa	C	Unknown		Not Reported
	Ergocalciferol	C			Not Reported
	Lantus	C			Not Reported
	Lozide	C			Not Reported
	Metformin	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Prednisone	C			Not Reported
	Ramipril	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	11624328	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1476711-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Synovitis; Tenderness; Tenderness; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Anakinra	C			Not Reported
	Ativan	C			Not Reported
	Benadryl	C			Not Reported
	Cortisone	C	Intramuscular		Not Reported
	Cortisone	C	Intra-arterial		Not Reported
	Dilaudid	C			Not Reported
	Enablex	C			Not Reported
	Lasix	C			Not Reported
	Leflunomide	C			Not Reported
	Loperamide	C			Not Reported
	Norflex	C			Not Reported
	Omnaris	C	Spray, Metered Dose		Not Reported
	Pantoprazole Sodium	C			Not Reported
	Rituxan	C	Intravenous (not otherwise specified)		Not Reported
	Vagifem	C	Vaginal		Not Reported
	Synthroid	C			Not Reported
	Abatacept	C			Not Reported
	Desoximetasone	C	Intra-arterial		Not Reported
	Darifenacin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	12696887	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1453		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab Hospira			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Onychomadesis; Onychomycosis	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Infliximab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	12702886	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016087030		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Increased; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Femur Fracture; Gait Disturbance; Gastric Disorder; Glycosylated Haemoglobin Increased; Heart Rate Increased; Hepatic Enzyme Increased; Infection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Neutrophil Count Increased; Off Label Use; Osteopenia; Pain; Pain In Extremity; Peripheral Swelling; Product Use Issue; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence;	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S		Unk		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qd		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	40milligram, 4 Every 1 Week		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	40 Milligram, Four Every One Week		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qd		Pfizer
	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	50 Milligram, 4 Every 1 Week		Pfizer
	Sulfasalazine			S	Oral	2000 Mg, Unk		Pfizer
	Sulfasalazine			S	Oral	2000 Milligram, Qd		Pfizer
	Sulfasalazine			S	Oral	1000 Milligram, Qd		Pfizer
	Sulfasalazine			S	Oral	2000 Milligram, Unk		Pfizer
	Sulfasalazine			S	Oral	2000 Milligram, Qd		Pfizer
	Sulfasalazine			S	Oral	1000 Milligram, Qd		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	2.5 Mg/Ml, Weekly		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk, Weekly (4 Every 1 Week)		Pfizer
	Methotrexate Sodium			S	Unknown	Unk, Weekly		Pfizer

Synovitis; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Methotrexate Sodium	S	Unknown	25 Df, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	25 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	20 Milligram, Qwk	Pfizer
	Arava	S	Oral	20 Mg, 1x/Day	Not Reported
	Arava	S		10 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk Unk, Qd	Not Reported
	Arava	S	Unknown	10 Milligram, Qd	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk Unk, Qd	Not Reported
	Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
	Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
	Plaquenil	S		200 Mg, Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported

Remicade	S		200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	800 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	200 Milligram, Unk	Not Reported
Orencia	S	Unknown	200 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Q4wk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tylenol	S	Unknown	Unk	Not Reported
Hydroxychloroquine/Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
Hydroxychloroquine/Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Acetaminophen	S	Unknown	325 Mg, Unk	Not Reported
Acetaminophen	S	Unknown	325 Milligram	Not Reported
Acetaminophen	S	Oral	650 Milligram	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Mg, Bid	Not Reported
Apo-Acetaminophen	S	Unknown	Unk	Not Reported
Apo-Acetaminophen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S		Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Acetaminophen And Codeine Phosphate	S	Unknown	Unk	Not Reported
Apo-Hydro	S		Unk	Not Reported

Apo-Hydro	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Mg, 1x/Day	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Apo Sulfasalazine	S	Unknown	2 G, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Amaryl	S	Unknown	Unk	Not Reported
Otezla	S	Unknown		Not Reported
Stelara	S	Unknown		Not Reported
Meloxicam	C	Unknown	Unk	Not Reported
Meloxicam	C	Unknown	Unk	Not Reported
Tylenol With Codeine No.3	C		Unk, As Needed	Not Reported
Tylenol With Codeine No.3	C		Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Celebrex	C	Oral	200 Mg, 2x/Day	Not Reported
Celebrex	C		200 Milligram, Bid	Not Reported
Hydromorphone Hcl	C		Unk	Not Reported
Methotrexate	C	Unknown	Unk Unk, Weekly	Not Reported
Methotrexate	C	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	C	Subcutaneous	Unk, 4 Every 1 Week	Not Reported
Methotrexate	C	Unknown	Unk, Qwk	Not Reported
Methotrexate	C	Unknown	25 Dosage Form, Qwk	Not Reported
Methotrexate	C	Subcutaneous	20 Milligram, Qwk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported

	Codeine	C	Unknown	Unk	Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Glyburide (Micronized)	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Lipitor	C	Unknown		Not Reported
	Metformin	C	Unknown	Unk Unk, Qd	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown		Not Reported
	Ramipril	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid (2 Every 1 Days)	Not Reported
	Xeljanz	C		50 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	12716207	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1611		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Onychoclasis; Synovitis; Tooth Loss	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

Leflunomide	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Zostavax	S	Subcutaneous	Not Reported
Zostavax	S	Intravenous (not otherwise specified)	Not Reported
Zostavax	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Varicella Zoster Vaccine Live	S	Unknown	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	C	Unknown	Not Reported
Cortisone	C	Unknown	Not Reported
Cortisone	C	Unknown	Not Reported
Diclofenac	C	Subcutaneous	Not Reported
Desoximetasone	C	Oral	Not Reported
Cortisone Acetate	C	Unknown	Not Reported
Zostavax	C	Unknown	Not Reported
Voltaren	C	Unknown	Not Reported

U.S. FOOD & DRUG ADMINISTRATION

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	12912801	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091708		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Oral	5 Milligram, Q12h		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Endocervical	400 Milligram		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone Acetate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Folic Acid			C	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Phosphate			C	Unknown	Unk		Not Reported
	Insulin			C	Oral	Drops Oral		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported

Acetaminophen And Codeine	C	Unknown			Not Reported
Celebrex	C	Unknown	2 Dosage Form, Qd		Not Reported
Metformin	C	Unknown	1 Dosage Form		Not Reported
Metformin	C	Unknown	2 Dosage Form, Bid		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	20 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	12933730	EXPEDITED (15-DAY)		DS, OT	CA-SA-2016SA201530		36 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Arava			S	Oral	10 Mg,Qd		Sanofi
	Sulfasalazine			S	Oral	500 Mg,Bid		Not Reported
	Sulfasalazine			S		1000 Mg, Bid		Not Reported
	Plaquenil			S	Oral	200 Mg,Unk		Sanofi
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Prednisone			S	Unknown	20 Mg,Qd		Not Reported
	Prednisone			S	Unknown	20 Mg,Qd		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate [Methotrexate Sodium]			S	Subcutaneous	20 Mg,Unk		Not Reported
	Methotrexate [Methotrexate Sodium]			S		Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg,Qw		Not Reported

Gold	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg, Qow		Not Reported
Orencia	S	Unknown	Unk Unk,Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	2 G,Qcy		Not Reported
Rituxan	S		2 Unk, Qcy		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	2 G, Q6m		Not Reported
Etanercept	S		50 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13519996	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038600			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Etanercept	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown			Not Reported
Cetirizine	S	Unknown	Unk		Not Reported
Folic Acid	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13520451	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-039843		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Vorhyaluronidase Alfa			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported

Elavil [Amitriptyline Hydrochloride]	C	Unknown			Not Reported
Hydrochlorothiazide	C	Unknown			Not Reported
Imitrex [Sumatriptan]	C	Unknown			Not Reported
Lyrica	C	Unknown			Not Reported
Premarin	C	Unknown			Not Reported
Tenormin	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported
Sumatriptan	C	Unknown			Not Reported
Amitriptyline	C	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13657154	EXPEDITED (15-DAY)		HO, OT	CA-SA-2017SA105779		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Erythema; Granuloma Skin;	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Leflunomide			S	Oral	20 Mg,Unk		Sanofi
	Leflunomide			S	Oral	20 Mg,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S		500 Mg		Not Reported
	Alendronate Sodium			S	Unknown	70 Mg,Qw		Not Reported
	Alendronate Sodium			S	Unknown	Unk Unk,Unk		Not Reported
	Codeine			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg		Not Reported
	Methotrexate			S	Oral	10 Mg,Qw		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Qw		Not Reported
	Methotrexate			S		12 Mg, Qw		Not Reported

Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Pruritus; Rash; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S		15 Mg	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Q4w	Not Reported
	Methotrexate	S		12.5 Unk	Not Reported
	Methotrexate	S		12 Mg	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Qw	Not Reported
	Methotrexate	S	Oral	10 Mg, Q4w	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Qw	Not Reported
	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Methotrexate	S	Oral	10 Mg, Q4w	Not Reported
	Methotrexate	S		12 Mg, Qw	Not Reported
	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	15.5 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	12 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	70 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Qw	Not Reported
	Methotrexate	S		17.5 Mg, Qw	Not Reported
	Methotrexate	S		15 Mg, Q4w	Not Reported
	Methotrexate	S		12 Mg, Q4w	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Q4w	Not Reported
	Alendronic Acid	S		70 Mg, Qw	Not Reported

Myochrysine	S	Intramuscular	50 Mg, Qm	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Qm	Not Reported
Myochrysine	S	Parenteral	50 Mg, Qm	Not Reported
Methotrexate Sodium	S	Oral	10 Mg, Qow	Not Reported
Actemra	S	Unknown	680 Mg,Qm	Not Reported
Actemra	S	Unknown	360 Mg,Qm	Not Reported
Actemra	S		380 Mg	Not Reported
Actemra	S		360 Mg, Qm	Not Reported
Enbrel	S	Unknown	50 Mg,Biw	Not Reported
Enbrel	S	Unknown	25 Mg,Biw	Not Reported
Enbrel	S		Unk	Not Reported
Enbrel	S		50 Mg, Qw	Not Reported
Humira	S	Subcutaneous	40 Mg,Qow	Not Reported
Humira	S		40 Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
Orencia	S	Unknown	780 Mg,Qw	Not Reported
Orencia	S		780 Mg	Not Reported
Orencia	S		780 Mg, Qw	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
Remicade	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Bid	Not Reported
Rituxan	S		Unk	Not Reported
Rituximab	S		1000 Mg, Bid	Not Reported
Tocilizumab	S		680 Mg, Q4w	Not Reported

	Ciclosporin	C	Unknown	150 Mg,Qd		Not Reported
	Prednisolone	C	Unknown	10 Mg,Unk		Not Reported
	Prednisone	C	Unknown	10 Mg,Qd		Not Reported
	Prednisone	C		10 Mg, Qd		Not Reported
	Xeljanz	C				Not Reported
	Alendronate Sodium	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13869108	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2444		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

Apo-Azathioprine	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Rituximab	S	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13869342	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017351180		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Bid		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Naprosyn			C	Unknown	Unk		Not Reported

Erythromycin	C		Unk		Not Reported
Morphine	C	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13870276	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017350057			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, Qwk		Not Reported
	Folic Acid			S	Unknown	5 Milligram, Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Folic Acid			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	13921480	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017372781		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Arthritis; Rheumatoid Factor Positive	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk (Prefilled Syringe)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid (1 Every 12 Hours)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Imuran	C	Unknown	Unk	Not Reported
	Arthrotec	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Azathioprine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14227055	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017506816			Female	CAN

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

Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel	S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium	S	Oral	20 Mg, Qwk		Pfizer
	Actemra	S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Arava	S	Unknown	20 Mg, Qwk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Meloxicam	S	Oral	7.5 Mg, Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Mobicox	S	Oral	7.5 Mg, Qd		Not Reported
	Sulfasalazine	C	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14227318	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017506298		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Pfizer
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14230778	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017510773		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Oral	1 G, Qd		Pfizer
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14570743	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0535		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Cystitis; Deformity; Depressed Mood; Encephalitis; Encephalitis Brain Stem; Fibromyalgia; Immunosuppression; Insomnia; Joint	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Celebrex			S	Unknown			Not Reported

Destruction; Loss Of Personal Independence In Daily Activities; Peripheral Swelling; Product Use Issue; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Seizure; Sepsis; Spinal Deformity	Arava	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Hydromorph Contin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	14632418	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-020711		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Codeine			S	Unknown			Not Reported
	Fosamax			S	Unknown	70 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	25 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Qwk		Not Reported

Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Methotrexate	S	Unknown	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Mg, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Mg, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	680 Mg, Qmo	Not Reported
	Tocilizumab	S	Unknown	360 Mg, Qmo	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Actemra	S	Unknown	360 Milligram, Qmo	Not Reported
	Actemra	S	Unknown	680 Milligram, Q4wk	Not Reported
	Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ciclosporin	S	Unknown	150 Milligram, Qd	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15215485	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018305256		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, 2 Times/Wk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 3 Times/Wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Q2wk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2x/Week		Not Reported
	Hydroxychloroquine			S	Unknown	400 Unk, Unk (Three In One Week)		Not Reported
	Leflunomide			S		Unk		Not Reported
	Prednisone			C	Unknown	20 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15246107	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015106204		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Blood Cholesterol Increased; C-Reactive Protein	Enbrel			S	Subcutaneous	25 Mg, 2x/Week		Pfizer
	Enbrel			S		25 Mg, 2x/Day		Pfizer

Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Enbrel	S	Subcutaneous	25 Mg, Cyclic Q2wk	Pfizer
	Enbrel	S		25 Mg, (3 Years, Freq: 2 Week; Interval: 1)	Pfizer
	Enbrel	S		25 Mg, Cyclic Q2wk	Pfizer
	Enbrel	S	Subcutaneous	25 Mg, Unk	Pfizer
	Xeljanz	S		Unk	Pfizer
	Methotrexate Sodium	S		25 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	25 Mg, 1x/Day	Pfizer
	Methotrexate Sodium	S	Vaginal	25 Mg, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S		25 Mg, 4 Times/Wk	Pfizer
	Methotrexate Sodium	S	Unknown	25 Mg, 11 Years, Freq: 1 Week; Interval: 1	Pfizer
	Methotrexate Sodium	S		Unk	Pfizer
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclic Every Two Weeks (Duration Reported As 365 Units Not Reported	Not Reported
	Humira	S	Unknown	200 Mg, 2x/Day	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	200 Mg, 2x/Day	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Monthly, Therapy Duration Reported As 61 (Unit Not Reported), (Freq: 1 Month; Interval: 1)	Not Reported
	Orencia	S		Unk, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
	Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported

Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Monthly, Therapy Duration Reported As 184 (Unit Not Reported),	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, 2x/Day	Not Reported
Hydroxychloroquine	S	Unknown	40 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	4 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	40 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 2x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Arava	S	Unknown	20 Mg, Daily	Not Reported
Arava	S		1 Mg, Every 1 Day	Not Reported
Arava	S		20 Mg, Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	1000 Mg, Day 1 &15	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone	C	Intramuscular	Unk	Not Reported

Cortisone	C	Intra-articular	Unk	Not Reported
Benadryl	C		Unk, As Needed	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Lasix	C		40 Mg, 3x/Day	Not Reported
Lasix	C	Unknown	Unk	Not Reported
Enablex [Darifenacin Hydrobromide]	C	Unknown	Unk, As Needed	Not Reported
Enablex [Darifenacin Hydrobromide]	C	Unknown	Unk	Not Reported
Ativan	C	Unknown	1 G, Daily At Bedtime	Not Reported
Ativan	C		1 Mg,Every 1 Day	Not Reported
Ativan	C	Unknown	Unk	Not Reported
Loperamide	C		2 Mg, 2x/Day	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk, 2x/Day	Not Reported
Norflex	C	Unknown	Unk, 2x/Day (Freq: 2 Day; Interval: 1)	Not Reported
Norflex	C		Unk	Not Reported
Omnaris	C	Unknown	Unk (Spray, Metered Dose)	Not Reported
Pantoloc	C	Unknown	Unk	Not Reported
Vagifem	C	Vaginal	Unk	Not Reported
Vagifem	C	Unknown	Unk	Not Reported
Dilaudid	C		4 Mg, Qd	Not Reported
Dilaudid	C	Unknown	4 Mg, Every 6 Hours	Not Reported
Dilaudid	C		4 Mg, Unk	Not Reported
Dilaudid	C	Unknown	Unk	Not Reported
Abatacept	C		Unk	Not Reported
Leflunomide	C		Unk	Not Reported
Kineret	C	Unknown	100 Mg, Unk	Not Reported

Anakinra	C	Unknown	100 Mg, Unk	Not Reported
Anakinra	C		100 Mg, Unk	Not Reported
Furosemide	C	Unknown	40 Mg, Three Every One Day	Not Reported
Furosemide	C	Unknown	40 Mg, 3x/Week	Not Reported
Furosemide	C	Unknown	Unk	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk (Freq: As Needed)	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk	Not Reported
Desoximetasone	C	Oral	Unk	Not Reported
Desoximetasone	C	Intramuscular	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported
Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	200 Mg, Unk	Not Reported
Morphine Sulfate	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported
Dexamethasone	C	Oral	Unk	Not Reported
Darifenacin	C	Unknown	Unk	Not Reported
Dyclone	C	Unknown	Unk	Not Reported
Kenalog	C	Intra-articular	40 Mg, Unk	Not Reported
Kenalog	C	Unknown	40 Milligram	Not Reported

	Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported
	Diphenhydramine Hydrochloride	C		Unk Unk, As Necessary (Freq: As Needed)	Not Reported
	Plantago Ovata	C	Unknown	Unk	Not Reported
	Dyclonine Hydrochloride	C		Unk	Not Reported
	Orphenadrine [Orphenadrine Hydrochloride]	C	Unknown	1 Dosage Form, Bid	Not Reported
	Pantoprazole Sodium	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Triamcinolone Acetonide	C	Intra-articular	40 Milligram, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15357865	EXPEDITED (15-DAY)		HO	PHHY2018DK086994		47 YR	Female	DNK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia Mycoplasmal	Azathioprine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Insulin			C	Unknown	Unk (On Pump)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15383851	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082919			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Intentional	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	15 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported

Product Use Issue; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Dispensing Error; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	200 Milligram, Qmo	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	200 Milligram, Qwk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Qwk	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	420 Milligram	Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Adalimumab	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous	15 Milligram, Q2wk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15617576	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555631-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Ill-Defined Disorder; Injection	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Site Reaction	Plaquenil	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Kevzara	S	Unknown	Not Reported
	Leflunomide	C		Not Reported
	Meloxicam	C		Not Reported
	Sulfasalazine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15619140	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555653-00		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Tramadol Hydrochloride			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15619319	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2554744-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lipitor	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15619584	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2555197-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Rheumatoid Arthritis; Wheelchair User	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide Apotex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15620413	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2555889-00		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15621393	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557319-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15627588	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2559128-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Pain; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Plaquenil			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Risedronate			C	Oral			Not Reported
	Arava			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15629381	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558926-00		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Humira			S	Subcutaneous			Not Reported

Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15660935	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016545757		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		50 Mg, Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S		4 Years		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Prednisone			C		10 Mg, 1x/Day		Not Reported
	Coversyl [Perindopril Erbumine]			C		Unk		Not Reported
	Hydroxychloroquine			C				Not Reported
	Cephalexine			C	Unknown	500 Milligram, Qid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15710031	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015280551		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15720388	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017364037		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Product Use In	Enbrel			S	Unknown	50 Milligram		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Etanercept			S	Unknown	Unk		Pfizer
	Tofacitinib Citrate			S	Oral	5 Mg, Bid		Pfizer
	Minocin			S	Unknown	Unk		Pfizer
	Minocycline Hcl			S	Unknown	Unk		Pfizer
	Salazopyrin			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer

Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Methotrexate Sodium	S	Unknown	15 Milligram, Qwk	Pfizer
	Methotrexate Sodium	S	Oral	Unk	Pfizer
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Subcutaneous	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Ustekinumab	S	Unknown	Unk	Not Reported
	Ustekinumab	S	Subcutaneous	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Myochrysine	S	Parenteral	Unk	Not Reported
	Myochrysine	S	Subcutaneous	Unk	Not Reported
	Myochrysine	S	Unknown	Unk	Not Reported
	Myochrysine	S	Intramuscular	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous drip	Unk	Not Reported
	Apremilast	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine	S	Unknown	Unk	Not Reported

Sulfate] Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Prednisone	C		Unk		Not Reported
Abatacept	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15781901	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017013508		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S		25 Mg, 2x/Week		Pfizer
	Enbrel			S	Unknown	25 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Apo-Leflunomide			S	Oral	20 Mg, Daily		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Unknown	300 Mg, Every 6 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, 1 Every 6 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Plaquenil	S		200 Mg, 2x/Day	Not Reported
Orencia	S		Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Rituxan	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S		Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Apo-Hydroxyquine	S		200 Mg, Bid	Not Reported
Hydroxychloroquine Sulfate	S		200 Mg, 2x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	1 Gram	Not Reported
Wellbutrin	C	Unknown	Unk	Not Reported
Sulfasalazine	C		1 G, 2x/Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15851696	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633984-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituxan	S		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15926889	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2651972-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Tablet		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz Xr	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15934368	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2655903-00		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain;	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Boric Acid			S	Unknown			Not Reported
	Disodium Edetate			S	Unknown			Not Reported
	Phenylephrine Hydrochloride			S	Unknown			Not Reported

Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Sodium Borate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rho D Immune Globulin	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Celebrex	C	Oral	Not Reported
	Ibuprofen	C	Oral	Not Reported
	Lipitor	C	Oral	Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Sulfasalazine	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15953507	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-012131		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Off Label Use; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	15995703	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2674768-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Vaginal	Dosage Form Solution		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported

Dilaudid	C	Unknown			Not Reported
Diphenhydramine	C				Not Reported
Enablex	C	Unknown			Not Reported
Lasix	C	Unknown			Not Reported
Loperamide	C				Not Reported
Norflex	C	Unknown			Not Reported
Omnaris	C	Unknown	Spray, Metered Dose		Not Reported
Pantoprazole Sodium Anhydrous	C				Not Reported
Synthroid	C	Unknown			Not Reported
Vagifem	C	Unknown			Not Reported
Pantoloc	C		(Enteric Coated)		Not Reported
Darifenacin Hydrobromide	C				Not Reported
Desoximetasone	C	Unknown			Not Reported
Benadryl	C	Unknown			Not Reported
Plantago Ovata	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16075583	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-012946		14 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Intentional Product Use Issue; Lymphoproliferative Disorder; Off Label Use; Off Label Use Of Device; Product Use In Unapproved Indication; Renal Cell Carcinoma	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Amlodipine Tablets			S	Unknown	Unk		Aurobindo
	Metformin Tablet			S	Unknown	Unk		Aurobindo
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Enalapril Maleate			S	Unknown	Unk		Not Reported
	Ferrous Fumarate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	100.0 Milligram, 1 Every 1 Month		Not Reported

Infliximab	S	Unknown	1000.0 Milligram, 1 Every 1 Month	Not Reported
Infliximab	S			Not Reported
Insulin	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S			Not Reported
Methotrexate	S			Not Reported
Nutropin	S	Subcutaneous	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Ranitidine	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Unknown	Unk	Not Reported
Androderm	S	Unknown	Unk	Not Reported
Protropin	S	Intramuscular	Unk	Not Reported
Acetazolamide	S	Unknown	Unk	Not Reported
Calcium Carbonate	S	Unknown	Unk	Not Reported
Cyclosporine	S	Unknown	Unk	Not Reported
Cyclosporine	S			Not Reported
Ferric Hydroxide Polymaltose Complex	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S			Not Reported
Insulin Human	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16332181	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019210438			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hyperhidrosis; Inappropriate Schedule Of Product Administration; Nausea; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Estradot			S	Transdermal	Unk, Weekly		Not Reported

	Hydroxychloroquine Sulfate		S		Unk	Not Reported
	Leflunomide		S	Unknown	20 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16334554	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018103158		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	10 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram		Pfizer
	Tofacitinib Citrate			S	Unknown	Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, (1 Every 2 Week(S))		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Sarilumab	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	40 Milligram		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Tocilizumab	S	Unknown	Unk		Not Reported
Rabeprazole Sodium	C	Oral	20 Mg, Qd		Not Reported
Prednisone	C		10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16343860	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019217974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Sulfasalazine			S	Unknown	2 Gram, Qd		Pfizer
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16387751	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-050993		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia;	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Rituximab			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported

Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Enbrel	S	Subcutaneous	25 Milligram, 2 Times/Wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	200 Milligram, Bid	Not Reported
	Humira	S	Unknown	1 Every 2 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	4 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
	Vagifem	C	Vaginal		Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qmo	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Ativan	C	Unknown	1 Gram	Not Reported
	Darifenacin	C	Unknown		Not Reported
	Desoximetasone	C	Oral		Not Reported
	Dilaudid	C	Unknown	4 Milligram	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown		Not Reported
	Furosemide	C	Unknown	40 Milligram, 3 Times/Wk	Not Reported
	Loperamide	C	Unknown	Unk, Bid	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Unk, Bid	Not Reported
	Omnaris	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Anakinra	C	Unknown	100 Milligram	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
	Codeine	C	Unknown	Unk	Not Reported

Darifenacin Hydrobromide	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	40 Milligram	Not Reported
Lasix [Furosemide]	C	Unknown	Unk	Not Reported
Morphine Sulfate	C	Unknown	Unk	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	200 Milligram	Not Reported
Leflunomide	C	Unknown		Not Reported
Desoximetasone	C	Intramuscular		Not Reported
Desoximetasone	C	Intra-arterial		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16537770	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-063625		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb
	Anakinra			S	Subcutaneous	100.0 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20.0 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported

Stenosis; Synovitis	Actemra	S	Intravenous (not otherwise specified)	8 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16600726	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-068199		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Joint Swelling; Off Label Use; Pain; Pemphigus; Rash; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown	50 Milligram		Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)		
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk Unk, Qd	Not Reported
	Prednisone	S	Unknown		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Hydrocortisone Acetate	S	Cutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
	Leflunomide	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16691316	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2885135-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Enbrel	S	Subcutaneous	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16802106	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019396164		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel			S		50 Mg, Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Ergocalciferol			C		Unk, Weekly		Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			C		Unk, 2x/Day		Not Reported
	Estrogel			C		0.6 %, 3x/Day		Not Reported
	Furosemide			C		40 Mg, 1x/Day		Not Reported
	Morphine			C	Unknown	Unk		Not Reported
	Potassium Chloride			C	Unknown	1500 Mg, 1x/Day		Not Reported
	Valsartan			C		320 Mg, 1x/Day		Not Reported
	Xalatan			C		50 Ug, 1x/Day		Not Reported
	Zingiber Officinale			C	Oral	500 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16817883	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019399548			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, 1x/Day		Pfizer
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Orencia			S	Unknown	750 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gold			S	Unknown	50 Milligram		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	16830577	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27321			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Morphine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17033629	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019493322			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Pantoprazole			S	Unknown	Unk		Pfizer
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Pfizer
	Morphine Hydrochloride			S	Unknown	Unk		Not Reported
	Cefixime			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			S	Oral	100 Milligram		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rivotril			S	Unknown	Unk		Not Reported
	Zantac			S	Unknown	Unk		Not Reported
	Zopiclone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17215587	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-39411		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered;	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported

Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Arava	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Cosentyx	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Otezla	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Simponi	S	Unknown	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Calcium	C	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unknown	Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Unknown	Not Reported
	Estradiol	C	Unknown	Unknown	Not Reported
	Estradiol	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Gravol Ginger	C	Unknown		Not Reported
	Morphine	C	Unknown	Unknown	Not Reported
	Potassium Chloride	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Xalatan	C	Unknown		Not Reported

Xalatan	C	Ophthalmic	Solution Ophthalmic		Not Reported
Xeljanz	C	Oral			Not Reported
Zingiber Officinale	C	Oral			Not Reported
Estrogel	C	Unknown			Not Reported
Estrogel	C	Unknown			Not Reported
Baclofen	C	Unknown			Not Reported
Gravol	C	Unknown	Unknown		Not Reported
Gravol Ginger Nighttime	C	Unknown	Unknown		Not Reported
Levaquin	C	Unknown			Not Reported
Tofacitinib Citrate	C	Oral			Not Reported
Acetaminophen	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17283605	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP005143		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	5 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Unk (Once In 4 Weeks)		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported

Methotrexate	S	Oral	Unk Unk, Q.Wk.		Not Reported
Rituxan	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Folic Acid	C	Unknown	5 Mg, Unk		Not Reported
Naproxen	C	Unknown	500 Mg, Bid		Not Reported
Simponi	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17390882	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018169790		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use	Enbrel			S		50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S		50 Mg, 1x/Day		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ciclosporin			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Neoral			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported

	Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S		Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
	Methotrexate Sodium	C		25 Mg, Weekly	Not Reported
	Hydroxychloroquine	C		200 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17422939	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010154		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every One Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every One Day		Not Reported
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Remicade			S	Unknown	300 Milligram, Q6wk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Wellbutrin			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17440627	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016346047		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Chest Pain; Contraindicated Product Administered; Discomfort; Drug Hypersensitivity; Drug Ineffective; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapy Non-Responder; Treatment Failure; Wound	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram (1 Every 24 Hours)		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Sulfasalazine			S	Oral	500 Milligram		Pfizer
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Pfizer
	Sulfasalazine			S		1 Gram, Bid		Pfizer
	Tofacitinib Citrate			S	Unknown	5 Milligram, Bid		Pfizer
	Tofacitinib Citrate			S	Unknown	5 Milligram, Bid		Pfizer
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Milligram, Qd		Not Reported
	Arava			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported
	Atasol [Paracetamol]			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported

Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	1 Milligram	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S		Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfathalidine	S	Oral	500 Milligram	Not Reported
Sulfathalidine	S	Oral	1000 Milligram, Bid	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Vitamin C	C		Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Alaskan Salmon Oil	C		Unk	Not Reported

	Glucosamine	C		Unk	Not Reported
	Lansoprazole	C		30 Mg, 2x/Day	Not Reported
	Ativan	C		2 Mg, 3x/Day, As Needed	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547396	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-059951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Cefixime			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Bisoprolol			S	Unknown	Unk		Not Reported
	Imuran			S	Oral	100 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Morphine			S	Unknown	Unk		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rivotril			S	Unknown	Unk		Not Reported
	Zantac			S	Unknown	Unk		Not Reported
	Zopiclone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547515	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568992			Female	CAN

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

Administered; Drug Ineffective; Rheumatoid Arthritis	Doxycycline Hyclate	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547563	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201804-001263			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pneumonia	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Pantoprazole			C				Not Reported
	Methotrexate			C		Unk		Not Reported
	Loperamide			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Bifidobacterium Bifidum			C		Unk		Not Reported
	Align			C		Unk		Not Reported

Actemra	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547565	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201804-001261			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Leflunomide			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Bifidobacterium Bifidum			C		Unk		Not Reported
	Loperamide			C		Unk		Not Reported
	Pantoprazole			C				Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547716	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201805-001646			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk, Tablet		Concordia
	Silver			S	Oral	Unk		Not Reported
	Sulfadiazine			S	Unknown	Unk		Not Reported
	Naprosyn			S	Unknown	Unk		Not Reported

Penicillin G Sodium	S	Unknown	Unk		Not Reported
Cimzia	S	Subcutaneous	Unk		Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	20 Mg, Weekly		Not Reported
Desoximetasone	C		Unk		Not Reported
Hydroxychloroquine	C		Unk		Not Reported
Tofacitinib Citrate	C		Unk		Not Reported
Tylenol [Paracetamol]	C		Unk		Not Reported
Cortisone	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17547762	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201804-001274			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Oral	Unk		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Erythromycin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk, Subcutaneous Solution		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Weekly		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Novo-Rythro			S	Unknown	Unk		Not Reported
	Risedronate Sodium			S	Oral	35 Mg, Weekly		Not Reported
	Marijuana			C		Unk		Not Reported
	Wellbutrin			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Ergocalciferol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548082	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023061		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Hand Deformity; Headache; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548119	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1391			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548364	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568773			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568775			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548444	EXPEDITED (15-DAY)		OT	NVSC2020CA073084		63 YR	Female	CAN

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

Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral	S	Subcutaneous	Unk	Novartis
	Neoral	S	Oral	Unk	Novartis
	Cyclosporine	S	Unknown	Unk	Novartis
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	1 Df, Qw	Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Plaquenil	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
	Rituxan	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548451	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567814		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous drip			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548465	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203461			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Kevzara			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetaminophen			C	Unknown	1300 Milligram Daily;		Not Reported
	Atacand			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Kevzara			C	Unknown			Not Reported
	Neurontin			C	Unknown	1800 Milligram Daily;		Not Reported
	Premarin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548476	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203253			Female	CAN

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

Arthralgia; Drug Ineffective; Fatigue; Joint Swelling; Leukopenia; Nausea; Pain In Extremity; Peripheral Swelling; Vomiting; Weight Decreased	Methotrexate	S	Unknown	2.8571 Milligram Daily;	Barr
	Adalimumab	S	Subcutaneous		Not Reported
	Arava	S	Unknown	20 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Calcium	C			Not Reported
	Fentanyl	C			Not Reported
	Folic Acid	C			Not Reported
	Magnesium	C			Not Reported
	Naproxen Sodium	C			Not Reported
	Pantoprazole	C			Not Reported
	Potassium	C			Not Reported
	Tramadol	C			Not Reported
	Vitamin D[Colecalciferol]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548477	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203601		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xalatan			S		50 Microgram Daily;		Not Reported
	Actemra			S	Unknown			Not Reported
	Dorzolamidehydrochloride/Timolol Maleate			C				Not Reported
	Ergocalciferol			C				Not Reported
	Estrogel			C		1.8 Percent Daily;		Not Reported
	Furosemide			C		40 Milligram Daily;		Not Reported
	Morphine			C				Not Reported
	Potassium Chloride			C		1500 Milligram Daily;		Not Reported

	Valsartan	C	320 Milligram Daily;		Not Reported
	Zingiber Officinale	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548478	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203488			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Topicort			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548712	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203265			Female	CAN

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

Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Treatment Failure	Methotrexate	S	Unknown		Barr
	Adalimumab	S	Subcutaneous		Not Reported
	Arava	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Tylenol Arthritis Pain 8h	C			Not Reported
	Desoximetasone	C		20 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548859	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203616		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Headache; Migraine; Off Label Use; Product Use Issue; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Barr
	Anakinra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Arava			S	Unknown	10 Milligram Daily;		Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548868	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203538			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Increased	Humira	S	Subcutaneous	Not Reported
	Otezla	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17549106	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204060		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Mass; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17549539	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020AMR042663			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glaucoma; Product Use Issue; Toxicity To Various Agents	Benlysta			S		Unk		Glaxosmithkline
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17549774	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2020-012083		56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Immune Reconstitution Inflammatory Syndrome; Neutrophilia; Whipple'S Disease	Methylprednisolone			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclobenzaprine			C	Unknown	Unk		Not Reported
	Celecoxib			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17550494	NON-EXPEDITED			NVSC2020US075268		21 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17550624	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021775			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug-Induced Liver Injury; Headache	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Azathioprine			S	Unknown	150 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	15 Milligram, Qwk		Not Reported
	Sulfasalazine			C	Unknown	500 Milligram, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17550986	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-08585		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood	Infliximab			S	Intravenous (not			Not Reported

Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure			otherwise specified)		
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown	Unknown	Not Reported
	Arava	S	Oral	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown		Not Reported
	Ciclosporin	S	Oral	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous, Single-Use Pre-Filled Syringe	Not Reported
	Cimzia	S	Subcutaneous	Single-Use Pre-Filled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution, Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Lyrica	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Simponi	S	Unknown	Unknown, Solution, Subcutaneous	Not Reported

Plaquenil	S	Unknown	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Prednisone	C	Unknown	Unknown		Not Reported
Piroxicam	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17551371	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021283			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia; White Blood Cell Count Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17551480	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023095		52 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Prednisone		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17551711	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021350		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C	Unknown	0.8 Milliliter		Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552311	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021309		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Prednisone	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Humira	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552323	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204244		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Warfarin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552337	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1204372		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Circumstance Or Information Capable Of Leading To Medication Error; Condition Aggravated; Intervertebral	Methotrexate			S	Unknown			Barr
	Apo-Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Discitis; Pyrexia; Synovitis; Transaminases Increased	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552354	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203747			Male	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552356	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204264			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552357	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204242		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552382	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1204376		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Hypertensive Heart Disease; Peripheral Swelling; Therapeutic Response Changed	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552406	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3324326-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Decreased	Xeljanz	S	Oral		Not Reported
	Haemophilus Influenzae	C		Vaccine	Not Reported
	Prevnar 13	C	Intramuscular		Not Reported
	Tetanus Vaccine	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552428	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021329		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Prednisone			C	Unknown	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552505	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021419			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Azathioprine	C	Unknown	50 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552708	EXPEDITED (15-DAY)		OT	NVSC2020CA073106		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not	8 Mg/Kg		Not Reported

			otherwise specified)		
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17552911	EXPEDITED (15-DAY)		OT	NVSC2020CA071955		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Unknown	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Unk		Not Reported

Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
Humira	S	Unknown	Unk		Not Reported
Methotrexate	S	Oral	20 Mg		Not Reported
Methotrexate	S	Oral	20 Unk		Not Reported
Orencia	S	Subcutaneous	125 Mg		Not Reported
Remicade	S	Unknown	3 Mg		Not Reported
Sulphasalazine	S	Oral	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17553141	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1027175			Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Recurrence; Drug Ineffective	Prednisone			S		Unk		Not Reported
	Hydroxychloroquine			S		200 Milligram, Qd For 3 Months		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	13816053	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017329621		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster;	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer

Nasopharyngitis; Therapeutic Product Effect Decreased	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Prednisone	C	Oral	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Arava	C		Unk	Not Reported
	Codeine	C	Unknown	Unk	Not Reported
	Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	13856372	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070330			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Label Use; Rash; Visual Impairment	Apo-Leflunomide		S	Unknown	20 Milligram, Qd	Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown	400 Milligram	Not Reported
	Methotrexate		S	Subcutaneous	15 Milligram, Qd	Not Reported
	Sulfasalazine		S	Oral	1 Gram, Qd	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	13929661	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2691		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14447073	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043369		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Arthropathy; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Finger Deformity; Limb Operation; Off Label Use; Pain; Peripheral Swelling; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Urticaria; Wrist Surgery	Arava			S	Oral	Unk		Sanofi
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rocuronium Bromide			S	Unknown	Unk Unk,Unk		Not Reported
	Rocuronium Bromide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Benzylpenicillin Sodium			S	Unknown	Unk Unk, Unk		Not Reported
	Phenoxymethylpenicillin Potassium			S	Unknown	Unk		Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Gold			S	Unknown	Unk Unk, Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Prednisone			C	Unknown	Unk Unk,Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14570820	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0542		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Hepatic Enzyme Increased; Liver Function Test Increased; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14630900	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2018AP007493		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased;	Apo-Prednisone			S	Unknown	Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Prednisone			S	Oral	Unk (Therapy Duration 365 Unit Unspecified)		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex

Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Leflunomide	S	Oral	Unk	Apotex
	Diclofenac Sodium	S	Unknown	Unk	Apotex
	Apo-Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk (Therapy Duration 365 Unit Unspecified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk (Therapy Duration: 365 Unspecified Unit)	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Bid (Therapy Duration 365 Unit Unspecified)	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	10 Mg, Unk	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported

	Plaquenil /00072602/	S	Oral	400 Mg, Qd	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	5 Mg, Bid	Not Reported
	Topicort /00028604/	S	Cutaneous	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Atasol /00020001/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14634899	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0737		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported
	Pantoprazol Sodium	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Tenofovir	C	Unknown	Not Reported
	Pantoprazol	C	Unknown	Not Reported
	Tenofovir Disoproxil	C	Unknown	Not Reported
	Pantoprazole Sodium	C	Unknown	Not Reported
	Pantoprazole Bluefish	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14788664	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1170			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Actemra		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Sarilumab		S	Unknown	Not Reported
	Kevzara		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	14836032	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-1328		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown	2x/Week		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15242994	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1069		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Product Use Issue; Rash; Skin Mass; Therapy Non-Responder	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported

	Prednisone Acetate	S	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15243408	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0441		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

Leflunomide	S	Unknown	Not Reported
Desoximetasone	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Methadone	S	Unknown	Not Reported
Ramipril	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Estrogel	C	Unknown	Not Reported
Calcium	C	Unknown	Not Reported
Xalatan	C	Unknown	Not Reported
Cosopt	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Vitamin D	C	Unknown	Not Reported
Jampk20	C	Unknown	Not Reported
Dorzolamide Hcl/Timolol Maleate	C	Unknown	Not Reported
Baclofen	C	Unknown	Not Reported
Levaquin	C	Unknown	Not Reported
Potassium Chloride	C	Unknown	Not Reported
Zingiber Officinale	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Cortisone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Estradiol	C	Unknown	Not Reported
Morphine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15293692	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1469		55 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15621032	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557288-00		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Photosensitivity Reaction; Stomatitis; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Oxycodone			S	Unknown	Cr Tablet		Not Reported
	Enbrel			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Not Reported
	Cannabis Sativa	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Actemra	C		Not Reported
	Enbrel	C		Not Reported
	Leflunomide	C		Not Reported
	Lyrica	C	Oral	Not Reported
	Oxycodone	C		Not Reported
	Sulfasalazine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15622638	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557282-00		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Rash; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Ergocalciferol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15622672	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557461-00		23 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15622680	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557508-00		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15624172	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556726-00		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15721414	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1025		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Loss Of Personal Independence In Daily Activities; Nodule; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Methotrexate Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15855189	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017546580		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Incorrect Route Of Product Administration; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	50 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Tofacitinib Citrate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Kevzara			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 10 Days		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q (Every)14 Day		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Q4wk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Rituxan			S	Intravenous (not	1 G, Unk		Not Reported

			otherwise specified)		
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Abatacept	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Milligram, Bid	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Adalimumab	S	Unknown	40 Milligram, 1 Every 14 Days	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	750 Milligram, Q4wk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	15956472	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190209141		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; C-Reactive Protein Increased; Crohn'S Disease; Decreased Appetite; Drug Ineffective; Drug Intolerance;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Exostosis; Fatigue; Foot Deformity; Hepatic Cirrhosis; Hypoaesthesia; Joint Dislocation; Joint Stiffness; Malaise; Mobility Decreased; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Rash; Red Blood Cell Sedimentation Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Visual Impairment	Cimzia	S	Subcutaneous	Single Use Pre Filled Syringe	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Otezla	S	Oral		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine /00072603/	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Etanercept	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Minocycline	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Sirukumab	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Bupropion Hydrochloride	C			Not Reported
	Hydromorphone Hydrochloride	C			Not Reported
	Bupropion	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16075445	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012854		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic	Alendronic Acid Tablets			S	Unknown	70 Milligram, 1 Every 1 Week		Aurobindo
	Alendronic Acid			S	Unknown	70 Milligram, Every Week		Aurobindo
	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	360 Milligram, 1 Every Month		Not Reported
	Actemra			S	Unknown	680 Milligram, 1 Every 4 Weeks		Not Reported
	Actemra			S	Unknown	2.68 Milligram, 1 Every 4 Weeks		Not Reported
	Actemra			S	Unknown	680.0 Milligram, 1 Every 1 Month		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every Week		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Every Week		Not Reported
	Enbrel			S	Unknown	50 Milligram, Every Week		Not Reported
	Enbrel			S	Unknown	25.0 Milligram, 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Every Week		Not Reported

Product Effect Decreased; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram, 1 Every 2 Weeks	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, 1 Every 4 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram, 1 Every 4 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 4 Weeks	Not Reported
	Methotrexate	S	Unknown	10.0 Milligram, 1 Every 4 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	15.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Oral	10.0 Milligram, 1 Every 4 Weeks	Not Reported
	Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
	Orencia	S	Unknown	760 Milligram, 1 Every 1 Week	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported

Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Methotrexate	S	Subcutaneous	12.0 Milligram, Every Week	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Ciclosporin	S	Unknown	150 Milligram, Once A Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, 1 Every 1 Month	Not Reported
Myochrysine	S	Parenteral	50.0 Milligram, 1 Every 1 Month	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every 1 Day	Not Reported
Tocilizumab	S	Unknown	360 Milligram, 1 Every 1 Month	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	680.0 Milligram	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1	Not Reported

				Week	
	Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	15.5milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5milligram, 1 Every 1 Week	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Once A Day	Not Reported
	Prednisone	C	Unknown	10 Milligram, 1 Every 1 Day	Not Reported
	Xeljanz	C	Unknown	5 Milligram, 2 Every 1 Day	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisolone	C	Unknown	10 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16075451	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012895		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug	Alendronic Acid Tablets			S	Unknown	70 Milligram, 1 Every 1 Week(S)		Aurobindo
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 1 Every 2 Week(S)		Not Reported
	Humira			S	Unknown	40 Milligram, 1 Every 1 Week(S)		Not Reported

Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, 1 Every 1 Week(S)	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, 1 Every 1 Week(S)	Not Reported
	Methotrexate	S	Unknown	10 Milligram, 1 Every 1 Week(S)	Not Reported
	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week(S)	Not Reported
	Methotrexate	S	Unknown	12 Milligram, 1 Every 1 Week(S)	Not Reported
	Orencia	S	Unknown	78 Milligram, 1 Every 1 Week(S)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	1000 Milligram, 2 Every 1day(S)	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	680 Milligram, 1 Every 1month(S)	Not Reported
	Actemra	S	Unknown	360 Milligram, 1 Every 1month(S)	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, 1 Every Week (S)	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, 1 Every Week (S)	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every Week (S)	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	50 Milligram, Once A Day	Not Reported
	Methotrexate	S	Subcutaneous	780 Milligram, Once A Day	Not Reported

Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	10 Milligram, 1 Every Week (S)		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Ciclosporin	C	Unknown	150 Milligram, 1 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16080822	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-012964			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, 2 Everey 1 Week		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	2 Milligram, Once A Day		Not Reported

	Hydromorphone		C	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16081413	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-013665		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Incorrect Route Of Product Administration; Infection; Nausea; Off Label Use; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral	100 Milligram, Two Times A Day		Aurobindo
	Celecoxib Capsules			S	Oral	Unk		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Every 1 Month		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown	Occlusive Dressing Technique		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported
	Enbrel			S	Unknown	50 Milligram, Every Week		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Every Week		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Every 3 Weeks		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Every 3 Weeks		Not Reported
	Nortriptyline Hydrochloride			S	Oral	10 Milligram		Not Reported
	Apo-Gabapentin			S	Oral	100 Milligram, Two Times A Day		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, 1 Every One Month		Not Reported
	Orencia			S	Intravenous (not	750 Milligram, Every 3		Not Reported

		otherwise specified)	Weeks	
Orencia	S	Vaginal	750 Milligram, Every 1 Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Every 4 Weeks	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Oxycontin	S	Unknown	Unk	Not Reported
Oxycontin	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
Sulfasalazine	S	Oral	2.5 Milligram, Once A Day	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Once A Day	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
Vitamin B1	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once A Day	Not Reported
Omega-3	S	Unknown	Unk	Not Reported
Omega-3	S	Unknown	1200 Milligram, Two Times A Day	Not Reported
Fentanyl Matrix	S	Unknown	Unk	Not Reported
Acetaminophen;Oxycodone Hydrochloride	C	Unknown	1 Dosage Form	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	70 Milligram, Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750.0 Milligram, 1 Every 4 Weeks	Not Reported
Actonel	C	Unknown	36 Milligram, Every Week	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	1 Dosage Form, Once A Day	Not Reported

Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Once A Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk Unk, Once A Day	Not Reported
Ergocalciferol	C	Unknown	400 International Unit, Once A Day	Not Reported
Ergocalciferol	C	Unknown	Unk Unk, Once A Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Two Times A Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	400 International Unit, Once A Day	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Once A Day	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Nasonex	C	Nasal	2 Dosage Form, Two Times A Day	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Milligram, Once A Day	Not Reported
Perphenazine	C	Oral	10 Milligram	Not Reported
Prednisone	C	Unknown	5 Milligram, Once A Day	Not Reported
Prednisone	C	Unknown	5 Gigabecquerel, Once A Day	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Once A Day	Not Reported
Tylenol	C	Oral	1000 Milligram, Once A Day	Not Reported
Vitamin B12	C	Unknown	Unk	Not Reported
Vitamin A	C	Unknown	Unk	Not Reported
Percocet	C	Unknown	Unk	Not Reported
Vitamin D 3	C	Unknown	Unk	Not Reported
Lomotil	C	Unknown	Unk	Not Reported
Oxycocet	C	Unknown	Unk	Not Reported
Vitamin C	C	Unknown	Unk	Not Reported

Biotin	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	300 Milligram	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Vitamin B3	C	Unknown	Unk	Not Reported
Vitamin B6	C	Unknown	Unk	Not Reported
Vitamin E	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200.0 Milligram, Two Times A Day	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	40 Milligram, Once A Day	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Milligram	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, Every Week	Not Reported
Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16205757	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020198		63 YR	Male	CAN

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

Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Amlodipine Tablets	S	Oral	Unk, 1 Every 1 Day	Aurobindo
	Amlodipine Tablets	S	Oral	5 Milligram, Once A Day	Aurobindo
	Asacol	S	Unknown	800 Milligram, 3 Every 1 Day	Not Reported
	Asacol	S	Unknown	800 Milligram, 3 Every 2 Day	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Diamicron	S	Unknown	Unk	Not Reported
	Gliclazide	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Ebastine	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intra-articular	Unk	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Oral	650 Milligram	Not Reported
	Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
	Atacand Plus	C	Unknown	Unk	Not Reported
	Crestor	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported

Amlodipine Besilate	C	Unknown	Unk, 1 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16206143	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-019772			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Celecoxib Capsules			S	Oral	200 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16347402	EXPEDITED (15-DAY)		OT	CA-SA-2019SA139156		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Sarilumab			S		20 Mg, Qow		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Oral			Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Sulfasalazine			S				Not Reported
	Esomeprazole Magnesium Trihydrate			S				Not Reported
	Nicotinamide			S				Not Reported
	Thiamine Hydrochloride			S				Not Reported
	Esomeprazole Sodium			S				Not Reported

Folic Acid	S			Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Actemra	S	Subcutaneous	162 Mg, Qw	Not Reported
Azathioprine	S			Not Reported
Ciclosporin	S			Not Reported
Enbrel	S			Not Reported
Adalimumab	C			Not Reported
Ergocalciferol	C			Not Reported
Hydroxychloroquine	C			Not Reported
Metformin	C			Not Reported
Nexium [Esomeprazole Sodium]	C			Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Magnesium	C		Unk	Not Reported
Gold	C			Not Reported
Vitamin A [Retinol]	C			Not Reported
Vitamin C [Ascorbic Acid]	C			Not Reported
Dexpanthenol	C			Not Reported
Esomeprazole Magnesium Trihydrate	C			Not Reported
Nexium [Esomeprazole Magnesium]	C			Not Reported
Riboflavin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16387694	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-029951		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia;	Alendronic Acid			S	Unknown	70 Milligram, Every Week		Aurobindo
	Actemra			S	Unknown	360 Milligram, 1 Every 1 Month(S)		Not Reported
	Actemra			S	Unknown	680 Milligram, Once A Day, 1 Every 1 Month(S)		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Every Week		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week(S)		Not Reported

Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Week(S)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	10.0 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	12.0 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram, Every Week	Not Reported
	Myochrysine	S	Intramuscular	50.0 Milligram, 1 Every 1 Month(S)	Not Reported
	Myochrysine	S			Not Reported
	Orencia	S	Unknown	780.0 Milligram, Every Week	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000.0 Milligram, Two Times A Day	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	10.0 Milligram, Daily	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16387698	EXPEDITED (15-DAY)		DS, HO, OT	CA-AUROBINDO-AUR-APL-2019-029940		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Response Decreased; Tongue Disorder; Ulcer	Alendronic Acid Tablets			S	Unknown	70 Milligram, Every Week		Aurobindo
	Alendronic Acid Tablets			S	Unknown	70 Milligram, 4 Every Week		Aurobindo
	Actemra			S	Unknown	2.68 Milligram,Once Every 4 Weeks		Not Reported
	Actemra			S	Unknown	360 Milligram,Once In A Month		Not Reported
	Actemra			S	Unknown	360 Milligram, Every Week		Not Reported
	Actemra			S	Unknown	680 Milligram, 1 Every 4 Weeks		Not Reported
	Apo-Ibuprofen			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apremilast			S	Unknown	60 Milligram, Two Times A Day		Not Reported
	Apremilast			S				Not Reported
	Apremilast			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week		Not Reported
	Enbrel			S	Unknown	25 Milligram, 1 Every 2 Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Infliximab			S	Oral	Unk		Not Reported

Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Methotrexate	S	Subcutaneous	12.0 Milligram,Once In Aweek	Not Reported
Methotrexate	S	Subcutaneous	15.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram,Once In A Week	Not Reported
Methotrexate	S	Unknown	70.0 Milligram,Once In Aweek	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram,Once In A Week	Not Reported
Methotrexate	S	Oral	10.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Unknown	12.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Unknown	10.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram,Once In A Week	Not Reported
Methotrexate	S	Unknown	10.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	15.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram,Once In A 2	Not Reported

			Weeks	
Methotrexate	S	Subcutaneous	15.0 Milligram,Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	10.0 Milligram,4 Every 1 Year	Not Reported
Methotrexate	S	Unknown	12 Milligram, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, 4 Every 1 Week	Not Reported
Mogadon	S	Oral	5 Milligram	Not Reported
Myochrysine	S	Parenteral	50 Milligram,Once In A Month	Not Reported
Nitrazepam	S	Oral	5 Milligram	Not Reported
Orencia	S	Unknown	780 Milligram,Once In A Week	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Sulfasalazine	S	Endocervical	500 Milligram	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Ibuprofen	S	Oral	600 Milligram, Once A Day	Not Reported
Tocilizumab	S	Unknown	360.0 Milligram,	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported

Ciclosporin	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Benadryl	C	Unknown	Unk		Not Reported
Colchicine	C	Unknown	Unk		Not Reported
Dexilant	C	Oral	Unk		Not Reported
Febuxostat	C	Unknown	Unk		Not Reported
Folic Acid	C	Unknown	Unk		Not Reported
Gravol	C	Unknown	Unk		Not Reported
Oxycodone	C	Unknown	Unk		Not Reported
Uloric	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16388032	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-030631		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal	Alendronic Acid Tablets			S	Oral	Unk		Aurobindo
	Alendronic Acid Tablets			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown	25 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone			S	Oral	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported

Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Enbrel	S	Subcutaneous	50 Milligram Once In A Week	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Golimumab	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
	Hydrocortisone Acetate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Once A Day	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Paracetamol	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Prednisone	S	Oral	25 Milligram	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram, Once A Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported

	Sarilumab	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Two Times A Day	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Topicort	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Two Times A Day	Not Reported
	Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16440716	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822523-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16729866	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2896155-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16739745	EXPEDITED (15-DAY)		OT	DE-ACCORD-152811			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Accord
	Pregabalin			S	Unknown	1 Df, Tid (1 - 1 - 1)		Not Reported
	Sildenafil/Sildenafil Citrate			S	Unknown	60 Milligram, Daily Dose		Not Reported

Incomplete; Therapy Cessation; Visual Impairment	Ambrisentan	S	Unknown	1 Dosage Form, Qd	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval	Not Reported
	Eliquis	S	Unknown	1 Df, Bid (1 - 0 - 1) 2.5 Mg Twice Daily	Not Reported
	Omeprazole	S	Oral	1 Df, 2x/Day (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour	Not Reported
	Spasmolyt	S	Unknown	1 Df, Qd 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day	Not Reported
	Volibris	S	Oral	30 Milligram, Qd	Not Reported
	Lyrica	S	Unknown	100 Milligram, Tid	Not Reported
	Apixaban	S		2.5 Milligram, Bid	Not Reported
	Trospium Chloride	S		30 Mg, Qd Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv	Not Reported
	Volibris	S	Oral	1 Dosage Form, Qd	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Ambrisentan	S	Unknown	30 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16758967	EXPEDITED (15-DAY)		OT	PHHY2019CA200445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure	Lopresor			S	Unknown	Unk		Novartis
	Ciprofloxacin			S	Unknown	Unk		Not Reported

Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash	Clindamycin	S	Unknown	Unk	Not Reported
	Codeine Phosphate	S	Unknown	Unk	Not Reported
	Enalapril Maleate	S	Unknown	Unk	Not Reported
	Losartan Potassium	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qd	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Isoniazid	S	Unknown	Unk	Not Reported
	Keflex	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Penicillin	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Cipro	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Hydroxyquinoline Sulfate	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16820448	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3439		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Unknown			Not Reported
	Zingiber Officinale			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	16866723	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3761			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17001941	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2989075-00		83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Dry Eye; Dry Mouth; Fatigue; Finger Deformity; Impaired Driving Ability; Macular Degeneration; Pain In Extremity; Rheumatoid Arthritis; Rheumatoid Nodule; Somnolence	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Levothyroxin			C				Not Reported
	Raloxifene			C				Not Reported
	Lidoderm			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17099946	EXPEDITED (15-DAY)		HO, OT	CA-COVIS PHARMA B.V.-2019COV00285		69 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Lower; Asthma; Atelectasis; Blood Disorder; Blood Immunoglobulin E Increased; Bronchial Wall Thickening; Bronchiolitis; Condition Aggravated; Cough; Dysphonia; Dyspnoea; Eosinophil Count Increased; Eosinophilic Granulomatosis With Polyangiitis; Fungal Infection; Infection Parasitic; Inflammation; Malaise; Oropharyngeal Pain; Pneumonia; Pneumonitis; Productive Cough; Secretion Discharge; Sinusitis; Skin Disorder; Sleep Disorder Due To A General Medical Condition; Spirometry Abnormal; Suprapubic Pain; Systemic Inflammatory Response Syndrome; Therapeutic Product Effect Incomplete; Underweight; Vasculitis; Weight Decreased; Wheezing	Alvesco			S	Respiratory (inhalation)	200 Mg, 1x/Day		Covis
	Omnaris			S	Nasal	50 Mg, Unk		Covis
	Pantoloc			S		40 Mg, Unk		Not Reported
	Ivermectin			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Unk		Not Reported
	Prednisone			S		50 Mg, Unk		Not Reported
	Salbutamol Sulfate			S		100 Mg, Unk		Not Reported
	Umeclidinium Bromide			S		62.5 Mg, Unk		Not Reported
	Zenhale			S		Unk, 2x/Day		Not Reported
	Sulfasalazine			C				Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17209128	EXPEDITED (15-DAY)		OT	CA-SA-2019SA353639			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Bone	Arava			S	Oral	Unk		Sanofi

Disorder; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Off Label Use; Pain; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tenosynovitis; Treatment Failure; Urticaria	Hydroxychloroquine Sulfate	S		Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Hydroxychloroquine Sulfate	S		Unk	Sanofi
	Methotrexate	S		Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Acetylsalicylic Acid/Caffeine/Codeine Phosphate Hemihydrate	S		Unk	Not Reported
	Rocuronium Bromide	S		Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sulfamethoxazole And Trimethoprim	S		Unk	Not Reported
	Orencia	S		Unk	Not Reported
	Penicillin G Sodium	S		Unk	Not Reported
	Penicillin V Potassium	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Prednisone	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17440774	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2018AP013701		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein	Minocycline			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	10 Mg, Unk		Not Reported

Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine	S	Oral	Unk	Apotex
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Leflunomide	S			Apotex
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S			Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Actemra	S			Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Unk	Not Reported
	Plaquenil /00072602/	S			Not Reported
	Plaquenil /00072602/	S			Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not	Unk	Not Reported

			otherwise specified)		
	Remicade	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S			Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Rituximab	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	Unk, Bid	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17523584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564553			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported

Pantoprazole		C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17526969	EXPEDITED (15-DAY)		HO	DE-CELLTRION INC.-2020DE020115			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anaemia; Arthralgia; Fall; Lower Limb Fracture; Occult Blood Positive; Osteoarthritis; Pruritus; Urinary Tract Infection	Rituximab (Unknown)			S	Unknown	500 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Unk		Not Reported
	Mabthera			S	Unknown	500 Mg, Unk		Not Reported
	Mabthera			S	Unknown	500 Mg, Unk		Not Reported
	Mabthera			S	Unknown	500 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17543429	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2497274-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fall; Fear Of Injection; Joint Swelling; Lower Limb Fracture; Malaise; Mammoplasty; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Urticaria	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17553452	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201805-001630			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Dizziness; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Fear Of Injection; Joint Swelling; Loss Of Personal Independence In Daily Activities; Oedema Peripheral; Pain In Extremity; Rheumatoid Arthritis; Stress; Vomiting	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Arava			S	Oral	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Domperidone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17553454	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201805-001673			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	25 Mg, Weekly		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

				otherwise specified)			
	Tofacitinib Citrate		S	Unknown			Not Reported
	Tofacitinib		S	Unknown	Unk		Not Reported
	Leflunomide		C				Not Reported
	Sulfasalazine		C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17553635	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567770			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554154	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205022		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	7.1429 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554157	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1205088			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Impaired Work Ability; Pyoderma Gangrenosum; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554179	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205203			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Moxifloxacin Hydrochloride			S	Oral			Teva
	Amoxicillin Trihydrate/Clavulanate Potassium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554197	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204339			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554199	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204340			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C				Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported

	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554209	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020112925		33 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Dysbiosis; Fatigue; Infection; Inflammation; Insomnia; Maternal Exposure During Pregnancy; Nausea; Pain; Psoriasis; Rheumatoid Factor Positive; Synovitis; Thyroid Disorder	Enbrel			S	Unknown	50 Milligram		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Pfizer
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	500 Milligram, Tid		Not Reported
	Naproxen			S	Unknown	500 Milligram, Tid		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Tramadol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554234	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205191		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554424	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1205198		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported

	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554449	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021302			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen Sodium			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral	5.0 Milligram 2 Every 1 Days		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554632	EXPEDITED (15-DAY)		OT	NVSC2020CA072976		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product	Neoral			S	Subcutaneous	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis

Administered; Drug Ineffective; Joint Swelling; Treatment Failure	Leflunomide		S	Unknown	Unk	Not Reported
	Methotrexate		S	Oral	20 Mg	Not Reported
	Methotrexate		S	Subcutaneous	20 Mg	Not Reported
	Orencia		S	Subcutaneous	125 Mg	Not Reported
	Plaquenil		S	Oral	20 Mg	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	3.0 Mg/Kg	Not Reported
	Actemra		S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Enbrel		S	Subcutaneous	50 Mg 1 Every 1 Weeks	Not Reported
	Xeljanz		C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554671	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565792		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17554843	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565710			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Imuran [Azathioprine]	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Neoral	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Citalopram Hydrobromide	C	Unknown	Not Reported
	Citalopram Hydrobromide	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555043	EXPEDITED (15-DAY)		HO	CA-ROCHE-2565721		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567695		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555303	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568898		73 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Alopecia; Anxiety; Asthenia; Depression; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Increased; Synovitis			otherwise specified)		
	Prednisone	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555514	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1412		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Pain; Rash; Rheumatoid Arthritis; Sleep Disorder	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Minocin			S	Unknown			Not Reported
	Minocycline Hcl			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported

Apo-Leflunomide	S	Unknown	Not Reported
Ustekinumab	S	Unknown	Not Reported
Ustekinumab	S	Subcutaneous	Not Reported
Tocilizumab	S	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Myochrysine	S	Parenteral	Not Reported
Myochrysine	S	Subcutaneous	Not Reported
Myochrysine	S	Unknown	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Stelara	S	Unknown	Not Reported
Stelara	S	Subcutaneous	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apremilast	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	C	Unknown	Not Reported
Abatacept	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555803	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1027221		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Pyrexia; Systemic Lupus Erythematosus	Prednisone			S		25 Mg, Qd		Not Reported
	Prednisone			S		(7.5 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		Unk (50 Mg Qd, Tapering Dose)		Not Reported
	Prednisone			S		15 Mg, Qd		Not Reported
	Prednisone			S		Unk (25 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		(15 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		Unk Unk (12.5 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		Unk Unk (10 Mg Qd, Dose Tapering)		Not Reported
	Tacrolimus			S		Unk Unk, Qd		Not Reported
	Mycophenolate Mofetil			S		Unk Unk, Qd		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Mylan
	Methylprednisolone			C		Unk (Pulses)		Mylan
	Rituximab			C		Unk		Mylan
	Immunoglobulin I.V			C		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17555876	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020114584			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Hepatitis B Reactivation; Inflammation; Malaise;	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer

Stomatitis; Weight Decreased	Sulfasalazine		S	Unknown	Unk	Pfizer
	Hydroxychloroquine Sulfate		S	Unknown	Unk	Not Reported
	Rituximab		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17556462	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2020M1027359			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea; Off Label Use; Respiratory Tract Infection; Vomiting	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Abatacept			S	Unknown	Unk		Mylan
	Roactemra			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557419	NON-EXPEDITED			NVSC2020US076875		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Tacrolimus			S	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557715	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205280			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported

Naproxen	C	Unknown			Not Reported
Naproxen	C	Unknown	250 Milligram Daily;		Not Reported
Acetaminophen	C	Unknown			Not Reported
Hydrocortisone Valerate	C	Unknown			Not Reported
Hydromorphone	C				Not Reported
Hydroxychloroquine Sulfate	C	Unknown			Not Reported
Lyderm	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Sodium Aurothiomalate	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557720	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205274		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin [Folinic Acid]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557725	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205434			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling;	Methotrexate			S	Unknown			Barr

Pain In Extremity; Peripheral Swelling	Arava	S	Oral	20 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557745	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205311		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Pharyngeal Oedema; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17557806	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205513			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Gait Disturbance; Headache; Influenza Like Illness; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Osteoarthritis; Rheumatoid Arthritis; Weight Fluctuation	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Actemra			C				Not Reported
	Enbrel			C	Subcutaneous	50 Milligram Daily;		Not Reported
	Humira			C	Subcutaneous			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17558048	NON-EXPEDITED		OT	NVSC2020US076308		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Diarrhoea; Gait Inability; Herpes Zoster; Rash; Skin Necrosis	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisolone			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2020	17558470	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020114627		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2 Every 1 Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 1 Every 1 Day		Pfizer
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported
	Tylenol [Paracetamol]			C	Unknown	Unk		Not Reported

Extremity; Pain In Jaw;
Peripheral Coldness;
Rhinorrhoea; Skin Mass

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	12956625	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2016AP014656		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Hypersensitivity; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Vomiting	Bisoprolol			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Apotex
	Norfloxacin			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Norflox			S	Unknown	400 Mg, Unk		Apotex
	Apo-Bisoprolol			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Levofloxacin			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Erythromycin			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Pregabalin			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd		Apotex
	Arthrotec			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Mg, Qd		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Mg, Every Two Months		Not Reported
	Humira			S	Subcutaneous	400 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unknown		Not Reported
	Meperidine Hcl			S	Unknown	Unk		Not Reported

Methotrexate	S	Oral	20 Mg, Q.Wk		Not Reported
Metronidazole	S	Unknown	5 Mg/Ml, Unk		Not Reported
Plaquenil /00072602/	S	Oral	400 Mg, Qd		Not Reported
Lyrica	S	Unknown	Unk		Not Reported
Arava	S	Unknown	Unk		Not Reported
Flagyl /00012501/	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
Erythromycin Estolate	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	13254292	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006753		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Sulfasalazine			S	Unknown	1 G, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lyrica			C	Oral			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

	Prednisone		C	Unknown	15 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	13516429	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037987			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Abatacept			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	13823542	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2252		65 YR	Female	CAN

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

Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Lyrica	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	13929206	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Rituximab	S	Intravenous drip	Not Reported
	Imuran	C	Unknown	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Azathioprine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	13988289	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-083265		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Orencia			S	Unknown	40 Milligram, Q2wk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Oral	2.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

	Cimzia	S	Unknown	Unk	Not Reported
	Methotrexate	C	Oral	10.0 Milligram, Qwk	Not Reported
	Methotrexate	C	Oral	15.0 Milligram, Qwk	Not Reported
	Methotrexate	C	Oral	2.5 Milligram, Qwk	Not Reported
	Methotrexate	C	Unknown	1 Dosage Form, Qwk	Not Reported
	Folic Acid	C	Oral	2.5 Milligram, Qd	Not Reported
	Pantoprazole	C	Oral	40 Milligram, Qd	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Zopiclone	C	Unknown	7.5 Milligram, Qd	Not Reported
	Tenofovir Disoproxil Fumarate	C	Oral	300 Milligram	Not Reported
	Pantoprazole Sodium Sesquihydrate	C	Unknown	Unk	Not Reported
	Tenofovir Disoproxil	C	Unknown	Unk	Not Reported
	Tenofovir	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	300 Milligram	Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	14223269	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021499			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	640 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported

	Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	14236211	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-3856			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Meloxicam			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mobicox			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	14545702	EXPEDITED (15-DAY)		OT	CA-ROCHE-1715783		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abdominal Pain Upper; Blood Pressure Diastolic Increased; Blood Pressure Diastolic Increased; Blood	Rituxan			S	Intravenous (not otherwise specified)	Last Dose: 21/Sep/2015, Most Recent Dose On 06/Jun/2017 (683 Mg)		Not Reported
	Rituxan			S	Intravenous (not	Last Dose: 21/Sep/2015		Not Reported

Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Increased; Blood Pressure Increased; Cough; Decreased Appetite; Epistaxis; Headache; Heart Rate Increased; Influenza Like Illness; Infusion Related Reaction; Infusion Site Pain; Medication Error; Nausea; Pain; Platelet Count Decreased; Pruritus; Pyrexia; Sensation Of Foreign Body; Vomiting; Weight Increased; Weight Increased				
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Methotrexate	C		Not Reported
	Folic Acid	C		Not Reported
	Atovaquone	C		Not Reported
	Alendronate	C		Not Reported
	Vit D3	C		Not Reported
	Diphenhydramine Hcl	C	Oral	Not Reported
	Diphenhydramine Hcl	C	Oral	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	14727278	EXPEDITED (15-DAY)		HO, OT	JP-GLAXOSMITHKLINE-JP2018JPN056741		45 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Cytomegalovirus Infection; Neutrophil Count Decreased; Pancreatitis	Belimumab			S	Intravenous drip	10 Mg/Kg, Every Two Weeks		Glaxosmithkline

Acute; Pneumocystis Jirovecii Pneumonia; White Blood Cell Count Decreased; White Blood Cell Count Decreased	Belimumab	S	Intravenous drip	10 Mg/Kg, Every Four Weeks	Glaxosmithkline
	Belimumab	S	Intravenous drip	10 Mg/Kg, Every Four Weeks	Glaxosmithkline
	Belimumab	S	Intravenous drip	10 Mg/Kg	Glaxosmithkline
	Belimumab	S	Intravenous drip	10 Mg/Kg, 1d	Glaxosmithkline
	Belimumab	S	Intravenous drip	10 Mg/Kg	Glaxosmithkline
	Furosemide	S	Oral	Unk	Glaxosmithkline
	Prednisolone	S	Oral	Unk	Glaxosmithkline
	Prednisolone	S	Oral	70 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	60 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	50 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	40 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Intravenous drip	40 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Intravenous drip	60 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	40 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	30 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	25 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	22.5 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	20 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	25 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	40 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	60 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	40 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	35 Mg, 1d	Glaxosmithkline
	Prograf	S	Oral	Unk	Not Reported
	Cellcept	S	Oral	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Meropenem	S	Intravenous drip	1 G, Tid	Not Reported
	Meropenem	S	Intravenous drip	Unk	Not Reported

Miraclid	S	Intravenous drip	300000 Iu, 1d	Not Reported
Omeprazole	S	Intravenous drip	40 Mg, 1d	Glaxosmithkline
Solu Medrol	C	Intravenous (not otherwise specified)	1000 Mg, 1d	Not Reported
Solu Medrol	C	Intravenous (not otherwise specified)	125 Mg, 1d	Not Reported
Valixa	C		Unk	Not Reported
Bonalon	C		Unk	Not Reported
Novorapid	C		Unk	Not Reported
Baktar	C		1 Df, We	Not Reported
Baktar	C			Not Reported
Daikenchuto	C		Unk	Not Reported
Sodium Picosulfate Hydrate	C		Unk	Not Reported
Tenelia	C		Unk	Not Reported
Pitavastatin Calcium	C		Unk	Not Reported
Cardenalin	C		Unk	Not Reported
Rabeprazole Sodium	C		Unk	Not Reported
Azilva	C		Unk	Not Reported
Amlodipine Besilate	C		Unk	Not Reported
Azelnidipine	C		Unk	Not Reported
Carvedilol	C		Unk	Not Reported
Bayaspirin	C		Unk	Not Reported
Sennoside	C		Unk	Not Reported
Insulin Glargine (Genetical Recombination)	C		Unk	Not Reported
Spironolactone	C		Unk	Not Reported
Humalog	C		Unk	Not Reported
Persantin-L	C		Unk	Not Reported
Feburic	C		Unk	Not Reported
Bonviva	C		Unk	Not Reported
Novolin R	C		Unk	Not Reported

	Trazenta	C	Unk	Not Reported
	Polaprezinc	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	15207582	NON-EXPEDITED			US-PFIZER INC-2018300600		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Cimzia			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	15605753	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3227		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Treatment Failure; Uveitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Sarilumab	S	Unknown	Not Reported
Tofacitinib	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Prednisone	C	Unknown	Not Reported
Rabeprazole Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	15675159	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-2495		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Arava	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Coversyl	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Cephalexine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	15962909	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013651		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Osteoarthritis; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200.0 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Day		Not Reported

Hydroxychloroquine Sulfate	C	Oral	200 Milligram, 2 Every 1 Day		Not Reported
Arava	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16075449	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012871		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Alendronic Acid Tablets			S	Unknown	70 Milligram, Once A Day		Aurobindo
	Alendronic Acid Tablets			S	Unknown	70 Milligram, Once A Day		Aurobindo
	Alendronic Acid Tablets			S	Oral	70 Milligram, Every Week		Aurobindo
	Actemra			S	Unknown	360 Milligram		Not Reported
	Actemra			S	Unknown	680 Milligram, Every Month		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week		Not Reported
	Enbrel			S	Unknown	50 Milligram, Every Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Everey 2 Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram,11 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Every Week		Not Reported

Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	15 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
Myochrysine	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
Orencia	S	Unknown	780 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	1000 Milligram, Two Times A Day	Not Reported
Myochrysine	S	Intramuscular	50 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram, Every Month	Not Reported
Alendronate Sodium	C	Unknown	70 Milligram, Every Week	Not Reported
Ciclosporin	C	Unknown	150 Milligram, Once A Day	Not Reported
Prednisone	C	Unknown	10 Milligram, Once A Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16082171	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06027		60 YR	Female	CAN

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

Bronchiectasis; Bursitis Infective; Crying; Infection; Inflammation; Leg Amputation; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Pneumonia; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Therapeutic Product Effect Incomplete	Infliximab	S	Unknown	Unknown	Not Reported
	Arava	S	Unknown		Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Remicade	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Acidophilus	C	Unknown	Unknown	Not Reported
	Aspirin	C	Unknown	Unknown	Not Reported
	Calcium	C	Unknown	Unknown	Not Reported
	Deflazacort	C	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Januvia	C	Unknown	Unknown	Not Reported
	Lidocaine	C	Topical		Not Reported
	Metronidazole	C	Unknown	Unknown	Not Reported
	Nitroglycerin	C	Unknown	Unknkown	Not Reported
	Pantoloc	C	Unknown	Unknown	Not Reported
	Pregabalin	C	Unknown		Not Reported
	Pregabalin	C			Not Reported
	Pregabalin	C			Not Reported
	Risedronate	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported

Rosuvastatin Calcium	C	Unknown	Unknown		Not Reported
Salbutamol	C	Unknown	Unknown		Not Reported
Salicylic Acid/Triamcinolone Acetonide	C	Intra-articular			Not Reported
Triamcinolone	C	Unknown			Not Reported
Tylenol	C	Unknown	Unknown		Not Reported
Xeljanz	C	Oral			Not Reported
Calcium Gluconate	C	Unknown	Unknown		Not Reported
Lactobacillus Acidophilus	C	Unknown	Unknown		Not Reported
Risedronate Sodium	C	Unknown	Unknown		Not Reported
Salicylic Acid	C	Unknown	Unknown		Not Reported
Triamcinolone Acetonide	C	Intra-articular	Suspension, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16095354	EXPEDITED (15-DAY)		OT	CA-BECTON DICKINSON-2019BDN00113		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State; Contraindicated Product Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder	Chlorhexidine			S				Becton Dickinson
	Chlorhexidine Gluconate			S				Becton Dickinson
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S				Not Reported
	Acetaminophen/Oxycodone Hydrochloride			S				Not Reported
	Acetaminophen/Oxycodone Hydrochloride/Oxycodone Terephthalate			S				Not Reported
	Act Oxycodone Cr			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg, 1x/Month		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg, 1x/Month		Not Reported
	Actemra			S		Unk		Not Reported

Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Actemra	S	Intravenous (not otherwise specified)	728.0 Mg; 4 Every 1 Week	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg; 4 Every 1 Week	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728.0 Mg, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, 1 Every 4 Week(S)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Mg, 1 Every 4 Week(S)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728.0 Mg, 1x/Month	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, 1x/Month	Not Reported
	Apo-Acetaminophen	S			Not Reported
	Chlorhexidine Gluconate Oral Rinse	S			Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S		Unk	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S			Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate Sodium	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycodone	S			Not Reported
	Oxycodone-Acetaminophen	S			Not Reported
	Oxycodone Cr	S			Not Reported
	Oxycodone Hydrochloride	S			Not Reported
	Oxycodone Terephthalate	S			Not Reported

Periogard	S			Not Reported
Periogard Alcohol Free	S	Buccal		Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Periarticular	Unk	Not Reported
Sulfamethoxazole	S			Not Reported
Sulfamethoxazole/Trimethoprim	S			Not Reported
Arava	C	Oral	20 Mg, 1x/Day	Not Reported
Arava	C		Unk	Not Reported
Cetirizine	C			Not Reported
Cetirizine Hydrochloride	C			Not Reported
Desogestrel/Ethinyl Estradiol	C			Not Reported
Hydroxychloroquine Phospate	C			Not Reported
Hydroxychloroquine Sulfate	C		400 Mg, 1x/Day	Not Reported
Ibuprofen	C			Not Reported
Pantoloc	C			Not Reported
Pantoprazole	C			Not Reported
Pantoprazole Sodium	C			Not Reported
Paracetamol	C			Not Reported
Paracetamol/Codeine	C			Not Reported
Plaquenil	C			Not Reported
Prednisone	C	Oral	7.5 Mg, 1x/Day	Not Reported
Prednisone	C		Unk	Not Reported
Reactine	C		10 Mg, 2x/Day	Not Reported
Reactine	C		Unk	Not Reported
Tylenol	C			Not Reported
Tylenol With Codeine	C			Not Reported
Tylenol #1	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16444894	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033815		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability;	Metformin			S	Unknown	Unk		Aurobindo
	Metformin			S				Aurobindo
	Cymbalta			S	Unknown	Unk		Not Reported

Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder; Weight Increased	Plaquenil	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Coumadin	S	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Xarelto	C	Unknown	Unk	Not Reported
	Imuran	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16770849	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1100415			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Actavis
	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Actavis
	Sildenafil Citrate			S	Unknown	60 Milligram Daily; 60 Milligram, Daily Dose		Actavis
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qwk		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Spasmolyt			S	Unknown	1 Df, Qd; 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day		Not Reported

	Spasmolyt	S	Unknown	30 Mg, Qd; Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv	Not Reported
	Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval	Not Reported
	Ambrisentan	S	Unknown	1 Dosage Form, Qd	Not Reported
	Ambrisentan	S	Unknown	30 Milligram Daily; 30 Milligram, Qd	Not Reported
	Lyrica	S	Unknown	300 Milligram Daily; 100 Milligram, Tid	Not Reported
	Apixaban	S		10 Milligram Daily; 2.5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	16866958	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-092201		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Abatacept			S	Unknown			Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)		
	Sarilumab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Kevzara	S	Unknown	Unk	Not Reported
	Mefenamic Acid	S	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Rabeprazole Sodium	C	Oral	20 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17124253	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-113880			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk (12.5 Milligram, 4 Every 1 Week)		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported

Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Human Immunoglobulin (Immunoglobulin Human Normal)	S	Unknown	Unk	Not Reported
	Human Immunoglobulin (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Infliximab	S	Unknown	5 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
	Naproxen	S	Unknown		Not Reported
	Prednisone	S	Oral	10 Milligram, Qd (5 Milligram, 2 Every 1 Day)	Not Reported
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17390832	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0682		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Meloxicam	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Tylenol	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17397400	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA032774			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17450142	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1058		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Hypersensitivity; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapy Non-Responder; Treatment Failure; Wound	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Alendronate Sodium	S	Oral	Not Reported
	Atasol [Paracetamol]	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine;Hydrochloride;Pseudo ephedrine	S	Unknown	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not	Not Reported

			otherwise specified)		
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfathalidine	S	Oral		Not Reported
	Sulfathalidine	S	Oral		Not Reported
	Topicort	S	Subcutaneous		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Vitamin C	C	Unknown		Not Reported
	Vitamin D	C	Unknown		Not Reported
	Alaskan Salmon Oil	C	Unknown		Not Reported
	Glucosamine	C	Unknown		Not Reported
	Lansoprazole	C	Unknown		Not Reported
	Ativan	C	Unknown	As Needed	Not Reported
	Salazopyrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17557868	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-013437		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Celecoxib Capsules			S				Aurobindo
	Anakinra			S	Unknown	100 Milligram		Not Reported

Incomplete	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram, Once A Day	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Apo-Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Azathioprine	S			Not Reported
	Celebrex	S	Unknown	200 Milligram	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Subcutaneous	25 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	1 Milliliter, Every Week	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, 1 Every 1 Month	Not Reported
	Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	7 Milligram, Once A Day	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, 1 Every 1 Month	Not Reported
	Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
	Altace	C	Unknown	5 Milligram	Not Reported
	Altace	C	Unknown	10 Milligram	Not Reported
	Apo-Gabapentin	C	Oral	100 Milligram	Not Reported
	Apo-Gabapentin	C	Unknown	300 Milligram	Not Reported
	Acetaminophen;Codeine	C	Unknown	Unk	Not Reported

Phosphate				
Atorvastatin Calcium	C	Oral	40 Milligram, Once A Day	Not Reported
Atorvastatin Calcium	C	Unknown	40 Milligram, Once A Day	Not Reported
Citalopram Hydrobromide	C	Unknown	20 Milligram	Not Reported
Conjugated Estrogens	C	Unknown	0.625 Milligram	Not Reported
Conjugated Estrogens	C	Unknown	20 Milligram	Not Reported
Cymbalta	C	Unknown	30 Milligram, Four Times/Day	Not Reported
Cymbalta	C	Unknown	60 Milligram	Not Reported
Cymbalta	C	Unknown	120 Milligram, Once A Day	Not Reported
Cipralex	C	Unknown	20 Milligram	Not Reported
Escitalopram	C	Unknown	10 Milligram	Not Reported
Estrace	C	Unknown	0.5 Milligram	Not Reported
Gabapentin	C	Oral	100 Milligram	Not Reported
Gabapentin	C	Unknown	3000 Milligram	Not Reported
Hydrochlorothiazide	C	Unknown	12.5 Milligram	Not Reported
Hydromorphone Hydrochloride	C	Oral	3 Milligram, Two Times A Day	Not Reported
Hydromorphone Hydrochloride	C	Oral	30 Milligram, Two Times A Day	Not Reported
Mupirocin	C	Topical	Unk	Not Reported
Pantoloc	C	Intravenous (not otherwise specified)	20 Milligram, Once A Day	Not Reported
Shark Liver Oil	C	Unknown	Unk	Not Reported
Tapentadol Hydrochloride	C	Unknown	50 Milligram	Not Reported
Taro-Mupirocin	C	Topical	Unk	Not Reported
Tramacet	C	Oral	Unk	Not Reported
Tramadol Hydrochloride	C	Oral	50 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17557974	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201805-001639			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Concordia
	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558021	EXPEDITED (15-DAY)		HO, OT	CA-ADVANZ PHARMA-GSH201711-006521			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	200 Mg, Bid, Tablet		Concordia
	Apo-Folic			S	Unknown	1 Dosage Form, Biw(Twice A Week)		Not Reported
	Apo-Gabapentin			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Esomeprazole Magnesium Trihydrate			S	Unknown	40 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, 4 Times In A Week		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558061	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-013432		59 YR	Female	CAN

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

Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Alendronic Acid Tablets	S	Unknown	Unk	Aurobindo
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10.0 Milligram	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	400.0 Milligram	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	5.0 Milligram	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20.0 Milligram, Once A Day	Not Reported
	Methotrexate	S	Oral	25.0 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400.0 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S			Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1000.0 Milligram, Two	Not Reported

				Times A Day		
	Sulfathalidine	S	Unknown	Unk		Not Reported
	Salazopyrin	C	Unknown	Unk		Not Reported
	Diclofenac	C	Unknown	50.0 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558697	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021515			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Cetrizine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558716	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567123		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Usp		Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			C				Not Reported
	Ciclosporin			C				Not Reported
	Minocycline			C				Not Reported
	Penicillamine			C				Not Reported
	Prednisone			C				Not Reported
	Actemra			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17558984	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201806-002196			Unknown	JPN

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

Pyrexia; Rash Maculo-Papular; Toxic Skin Eruption; Vitreous Detachment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil		S	Oral	200 Mg, Qd (Film-Coated Tablet)	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil		S	Oral	100 Mg, Qod (Film-Coated Tablet)	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil		S	Oral	200 Mg, Qod (Film-Coated Tablet)	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil		S	Oral	200 Mg, Qd (Film-Coated Tablet)	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil		S	Oral	200 Mg, Qod (Film-Coated Tablet)	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil		S	Oral	400 Mg, Qod (Film-Coated Tablet)	Concordia
	Onetram		C		Unk	Not Reported
	Nexium		C		Unk	Not Reported
	Prorenal		C		Unk	Not Reported
	Seroquel		C		Unk	Not Reported
	Magnesium Oxide		C		Unk	Not Reported
	Cefalexin		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559013	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-08978		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Rheumatoid Arthritis; Treatment Failure	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported

Azathioprine	S	Unknown	Unknown		Not Reported
Certolizumab Pegol	S	Unknown	Unknown		Not Reported
Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Unknown		Not Reported
Enbrel	S	Subcutaneous	Unknown		Not Reported
Gold	S	Unknown	Unknown		Not Reported
Hydroxychloroquine	S	Oral	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unknown		Not Reported
Imuran	S	Unknown	Unknown		Not Reported
Leflunomide	S	Oral			Not Reported
Methotrexate	S	Unknown	Unknown		Not Reported
Plaquenil	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559017	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-08970		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use;	Etanercept			S	Unknown	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Imuran	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Parenteral	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Oral	Unknown	Not Reported
	Methotrexate	S	Parenteral	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Methotrexate	S	Oral	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Arava	C	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown	Unknown	Not Reported
	Tofacitinib	C	Unknown	Unknown	Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559162	EXPEDITED (15-DAY)		OT	CA-ROCHE-2569481		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Drug Intolerance; Glaucoma	Cimzia		S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Methotrexate		S	Oral		Not Reported
	Orencia		S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown		Not Reported
	Simponi		S	Subcutaneous		Not Reported
	Lyrica		C	Oral		Not Reported
	Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559216	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021540		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559217	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568742			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559409	EXPEDITED (15-DAY)		DS	CA-ROCHE-2568722		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported

	Remicade		S	Unknown	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Cymbalta		C		Not Reported
	Folic Acid		C		Not Reported
	Xeljanz		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559478	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565794		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559517	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568861		89 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia;	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

Rheumatoid Arthritis	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Naprosyn [Naproxen]	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Vioxx	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559606	EXPEDITED (15-DAY)		HO, OT	US-APPCO PHARMA LLC-2081773		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559853	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021632		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported

Prednisone	S	Oral	5 Milligram, Qd		Not Reported
Sulfasalazine	S	Unknown	1000 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559938	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2020-1439		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Rhinorrhoea; Skin Mass	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559980	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021788		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not			Not Reported

Arthritis; Therapeutic Product Effect Incomplete			otherwise specified)		
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Naproxen	C	Unknown	500 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559985	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566109			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17559994	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021821			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported

Pneumonia	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560048	EXPEDITED (15-DAY)		OT	GB-ACCORD-176336		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Atorvastatin/Atorvastatin Calcium			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown			Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560201	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560261	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-202003001629			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glossodynia; Hangnail; Nail Avulsion; Onychoclasis; Sjogren'S Syndrome; Stomatitis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk, Resumption		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560263	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202003001668			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema; Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg		Concordia
	Nivaquine			C		100 Mg		Not Reported
	Nivaquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560475	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021879			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulphate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown	5 Milligram, Q12h	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560623	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567748		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Penicillamine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

Agents; Treatment Failure; Vasculitis; Weight Decreased	Simponi	S	Subcutaneous	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Not Reported
	Doxycycline	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Tobramycin	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560672	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021576		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560673	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021952		69 YR	Male	CAN

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

Abdominal Discomfort; Carotid Arteriosclerosis; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Off Label Use; Osteoarthritis; Rectal Haemorrhage; Rheumatoid Arthritis; Thyroid Cancer	Orencia	S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Methotrexate	S	Intra-arterial			Not Reported
	Methotrexate	S	Oral			Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram		Not Reported
	Sulfasalazine	S	Oral			Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Xeljanz	S	Oral	2.5 Milligram, Qd		Not Reported
	Enbrel	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561009	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020118255			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Drug Ineffective	Methotrexate Sodium			S	Unknown			Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561066	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020118198			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer

	Atorvastatin Calcium	S		Unk	Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]	S		200 Mg, 2x/Day	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Monthly	Not Reported
	Alprazolam	C		1 Mg, Unk	Not Reported
	Folic Acid	C		5 Mg, Unk	Not Reported
	Naprosyn [Naproxen]	C		500 Mg, 2x/Day	Not Reported
	Pantoloc [Pantoprazole]	C		Unk	Not Reported
	Prednisone	C		5 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561096	EXPEDITED (15-DAY)		OT	CA-SHIRE-CA202009727			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Product Effect Incomplete	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)			Shire
	Azathioprine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561109	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008889			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Leukopenia	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Etanercept			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561204	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021856		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown	325 Milligram		Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram, 4 Every One Week		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Q12h		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous	2000 Milligram		Not Reported
	Leflunomide			S	Unknown	200 Milligram, Qd		Not Reported
	Tylenol			S	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown	Unk, Qwk		Not Reported
	Synthroid			C	Unknown			Not Reported

	Tylenol	C	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561711	EXPEDITED (15-DAY)		HO	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Intentional Product Use Issue; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	1.5 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561810	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1206362		61 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Influenza; Injection Site Pain; Pain; Pain In Extremity; Rheumatoid Arthritis; Skin Burning Sensation; Skin Exfoliation	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydromorph Contin			C				Not Reported
	Prednisone			C				Not Reported
	Allopurinol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561811	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1206466			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Alopecia	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C				Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561822	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206400		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breath Sounds Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not			Not Reported

			otherwise specified)	
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Acetylsalicylic Acid	C	Unknown		Not Reported
Alprazolam	C	Unknown		Not Reported
Amlodipine	C	Unknown	5 Milligram Daily;	Not Reported
Asa	C	Unknown		Not Reported
Bisoprolol Fumarate	C	Unknown		Not Reported
Celebrex	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Metformin	C	Unknown		Not Reported
Morphine Sulfate	C	Unknown		Not Reported
Morphine Sulfate	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Paroxetine	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Risedronate Sodium	C	Unknown		Not Reported
Simvastatin	C	Unknown		Not Reported
Telmisartan	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561842	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206475			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock;	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Synovitis; White Blood Cell Count Decreased	Sulfasalazine		S	Unknown	2 Gram Daily;	Not Reported
	Tofacitinib		S	Unknown	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561854	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206317		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561863	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206324		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported

	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561870	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206272		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Arthralgia; Condition Aggravated; Dry Eye; Fatigue; Feeling Abnormal; Gastrointestinal Disorder; Headache; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete; Thirst; Tremor; Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Barr
	Arava			S	Oral	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Apo-Naproxen			C		1000 Milligram Daily;		Not Reported
	Apo-Prednisone			C				Not Reported
	Desoximetasone			C				Not Reported
	Ergocalciferol			C	Oral			Not Reported
	Folic Acid			C		1 Milligram Daily;		Not Reported
	Leucovorin Calcium			C				Not Reported
	Pantoprazole Magnesium			C		40 Milligram Daily;		Not Reported
	Pantoprazole Magnesium			C		1 Dosage Forms Daily;		Not Reported
	Vitamin C [Ascorbic Acid]			C	Oral			Not Reported
	Wellbutrin			C		300 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17561877	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206389			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Loss Of Personal Independence In Daily Activities; Treatment Failure	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562040	NON-EXPEDITED			US-PFIZER INC-2020117515		79 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Diarrhoea; Drug Hypersensitivity; Nausea; Vomiting	Ciprofloxacin			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562437	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022525			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported

	Loperamide	C	Oral		Not Reported
	Pantoprazole	C	Unknown	Unk, Tid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562446	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020116277		60 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Visual Acuity Reduced	Dobupal			S		Unk Unk, 1x/Day (1/24)		Pfizer
	Hydrochlorothiazide/Losartan Potassium			S		50 Mg/12.5 Mg		Not Reported
	Eutirox			S		Unk Unk, 1x/Day (1/24)		Not Reported
	Dolquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562460	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567649			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Dyspepsia	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	300-400 ; Ongoing		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Ongoing		Not Reported
	Simponi			S	Unknown	Ongoing		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562480	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206591		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Androgenetic Alopecia; Aphthous Ulcer; Blood	Methotrexate			S	Unknown			Barr

Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Blood Pressure Systolic Increased; Diffuse Alopecia; Drug Ineffective; Heart Rate Decreased; Infection; Infusion Related Reaction; Nasopharyngitis; Rash; Stomatitis; White Blood Cell Count Decreased	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Asa	C	Unknown	Not Reported
	Bisoprolol	C	Unknown	Not Reported
	Candesartan	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17562971	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022558		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17563672	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022540			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17563694	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022541			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

	Prednisone			S	Unknown				Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17563850	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021523		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported
	Synthyroid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	12928888	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8.0 Millilitre Per Kilogram		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Anakinra			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qh		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qcycle		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qh		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	35 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram, Qcycle		Not Reported

Simponi	S	Subcutaneous	Unk	Not Reported
Actonel	S	Oral	35 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	300 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk, Qwk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qh	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qcycle	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	1 Dosage Form, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Risedronate Sodium	S	Unknown	35 Milligram, One Every One Week	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Oral	10 Milligram, Qd	Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Risedronic Acid	S	Unknown	35 Milligram, Qwk	Not Reported
Hydroxychloroquine	C	Unknown	300 Milligram, Qd	Not Reported
Risedronate	C	Unknown		Not Reported
Methotrexate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	13519848	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-000478		56 YR	Male	CAN

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

C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Off Label Use; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Stomatitis; Urticaria	Orencia	S	Unknown		Bristol Myers Squibb
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
	Minocycline Hcl	S	Unknown	Unk	Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	400 Gram	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Prednisone	C	Unknown	Unk, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Q2wk	Not Reported
	Actemra	C	Unknown		Not Reported
	Cannabis Sativa	C	Unknown		Not Reported
	Enbrel	C	Unknown		Not Reported
	Oxycodone	C	Unknown	10 Milligram	Not Reported
	Sulfasalazine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	13594604	EXPEDITED (15-DAY)		OT	CA-ROCHE-1941652		42 YR	Female	CAN

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

Drug Ineffective; Hepatic Enzyme Increased	Rituxan		S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Apo-Hydroxyquine		S	Unknown		Not Reported
	Arava		S	Unknown		Not Reported
	Enbrel		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Orencia		S	Intravenous (not otherwise specified)		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	13901217	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170125543		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hepatotoxicity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Pain; Pulmonary	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Kineret			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Oral	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Not Reported
	Actonel	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported
	Risedronate	S	Unknown	Not Reported
	Risedronate	S	Unknown	Not Reported
	Risedronate Sodium	S	Other	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Adalimumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	14326215	NON-EXPEDITED			US-AMGEN-USASP2017190208		57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Asa			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Macrobid [Nitrofurantoin]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	14471157	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-004461		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain;	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous	Unk Df, Unk		Not Reported
	Actemra			S	Unknown	160 Mg, Unk		Not Reported
	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported

Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Hydroxychloroquine Sulphate	C	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intra-articular	80 Milligram, Qd	Not Reported
	Diclofenac	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15385213	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184735		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

	Xeljanz			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15565611	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-CELLTRION INC.-2018CA023567			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	5 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

	Hydroxychloroquine Sulfate			S	Oral	Unk			Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Hydroxychloroquine			S	Unknown	Unk			Not Reported
	Hydroxychloroquine			S	Oral	Unk			Not Reported
	Arava			C	Unknown	Unk			Not Reported
	Arava			C	Oral	Unk			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15620814	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556952-00		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Actonel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15622519	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557164-00		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Treatment Failure; Tremor	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Adalimumab			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Pantoprazole Magnesium			C		Enteric Coated		Not Reported
	Tenofovir Disoproxil Fumarate			C	Oral			Not Reported

	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C			Not Reported
	Pantoprazole Sodium Anhydrous	C			Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Pantoprazole Bluefish	C			Not Reported
	Tenofovir Disoproxil	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15625325	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557482-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Rituxan			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15629661	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557290-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Asa			C				Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C	Unknown			Not Reported
	Nitroglycerin			C				Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported
	Gabapentin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15635193	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105819			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Abnormal; Shoulder Arthroplasty; Treatment Failure	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral		Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Methotrexate	C	Oral	25 Mg, Qwk	Not Reported
	Prednisone	C	Unknown	30 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	15741776	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20181218371		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Bronchiectasis; Disease Susceptibility; Drug Ineffective; Joint Swelling; Myocardial Infarction; Pulmonary Fibrosis; Toxicity To Various Agents; Upper Limb Fracture	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Procytox			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16075459	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012877		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Alendronic Acid Tablets			S	Unknown	70 Milligram, 1 Every Week		Aurobindo
	Actemra			S	Unknown	680 Milligram, 1 Every 4 Week		Not Reported
	Actemra			S	Unknown	360 Milligram, 1 Every Week		Not Reported
	Actemra			S	Unknown	360 Milligram, 1 Every Month		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Every Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, Every Week		Not Reported
	Methotrexate			S	Unknown	10 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Every Week		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Unknown	12 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Every Week		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, 1 Every		Not Reported

				Month	
	Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram, Two Times A Day	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16081389	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013165		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Risedronate Tablet			S	Unknown	35 Milligram, Every Week		Aurobindo
	Risedronate Tablet			S	Oral	35 Milligram, Every Week		Aurobindo
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	300 Milligram, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	1 Dosage Form, Once A Day		Not Reported
	Leflunomide			S	Oral	20 Milligram, Once A Day		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Once A Day		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Once A Day		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram		Not Reported
	Plaquenil			S	Oral	300 Milligram, Once A Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	35 Milligram, Every Week		Not Reported

	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Cyclical (1 Every 1 Day)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk,Once A Day	Not Reported
	Actonel	S	Unknown	35 Milligram, Every Week	Not Reported
	Hydroxychloroquine	S	Unknown	Unk,Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram	Not Reported
	Anakinra	S	Subcutaneous	100.0 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Oral	5.0 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16122724	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-026025			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Endocervical			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	20 Nanogram	Not Reported
	Meloxicam	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk, Qwk	Not Reported
	Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported
	Methotrexate	C	Unknown	Unk, Q4wk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Acetaminophen & Cod. Phosp.	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16145460	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.-2019CA019978			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Weekly		Not Reported
	Enbrel			S	Unknown	50 Mg, Weekly, Unknown		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Q2wk (End Date: 2011)		Not Reported
	Enbrel			S	Unknown	25 Mg, 2x/Week (End Date: 2011)		Not Reported

Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, Unk (1 Every 2 Week)	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Etanercept	S	Unknown	25 Milligram, 2 Times/Wk	Not Reported
	Etanercept	S	Unknown	50 Mg, Weekly	Not Reported
	Celebrex	S		Unk	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	15.5, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	15mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	17.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported

Methotrexate Sodium	S	Oral	25 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Oral	Unk	Not Reported
Methotrexate Sodium	S	Oral	12.5 Mg, Unk	Not Reported
Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Oral	12.5 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Subcutaneous	15 Mg, Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	70 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Not Reported
Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Not Reported
Methotrexate Sodium	S	Unknown	15.5 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Mg, Q4wk	Not Reported
Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q4wk	Not Reported
Methotrexate Sodium	S	Subcutaneous	12 Mg, Weekly	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Mg, Monthly	Not Reported
Simponi	S	Unknown	360 Mg, Monthly	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Daily	Not Reported
Leflunomide	S		20 Mg, 5 Days Out Of 7	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Unk, Unk	Not Reported

Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Every 2 Weeks	Not Reported
Humira	S	Subcutaneous	40 Mg,Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 1x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Daily	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Actemra	S	Unknown	360 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, (Every 4 Weeks)	Not Reported
Actemra	S	Unknown	2.68 Mg, Q4wk,	Not Reported
Actemra	S	Unknown	360 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, Unk	Not Reported
Orencia	S	Unknown	760 Mg, Weekly	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	760 Mg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Monthly	Not Reported

Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
Myochrysine	S	Parenteral	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Cyclic (Once Every Two Weeks)	Not Reported
Myochrysine	S	Unknown	50 Mg, Monthly	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Mg, Weekly	Not Reported
Tocilizumab	S	Unknown	380 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Week	Not Reported
Hydroxychloroquine	S	Oral	20 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	200 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Weekly	Not Reported
Rituximab	S	Unknown	1000 Mg, 2x/Day	Not Reported
Adalimumab	S	Subcutaneous	40 Mg, Q2wk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	70 Mg, Weekly	Not Reported
Prednisone	C	Unknown	10 Mg, 1x/Day	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Mg, (Every 2 Hours)	Not Reported
Prednisone	C	Unknown	Unk	Not Reported

	Prednisone	C	Unknown	10 Mg, (Every 2 Hours)	Not Reported
	Prednisone	C		10 Mg, Unk	Not Reported
	Cyclosporin	C	Unknown	150 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisolone	C		Unk	Not Reported
	Alendronate	C	Unknown	Unk	Not Reported
	Alendronate	C	Unknown	70 Mg, Weekly	Not Reported
	Alendronate	C	Unknown	70 Mg, Weekly	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16211394	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020276		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung;	Meloxicam			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	160 Milligram, Every Week		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Depo Medrol			C	Intra-articular	80 Milligram		Not Reported
	Depo Medrol			C	Intramuscular	80 Milligram, Once A Day		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Oral	Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk		Not Reported

Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Prednisone		C	Unknown	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Two Times A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16216662	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020655		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Risedronate			S	Unknown	35 Milligram, Every Week		Aurobindo
	Risedronate			S	Unknown	16.35 Milligram, 1 Every 2 Weeks		Aurobindo
	Risedronate Tablet			S	Oral	35 Milligram, 1 Every 1 Week		Aurobindo
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actonel			S	Unknown	35 Milligram, 1 Every 1 Week		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Cyclical		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Once A Day		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, One Every One Hour		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every Two		Not Reported

			Weeks	
Hydroxychloroquine	S	Unknown	300 Milligram, Once A Day	Not Reported
Hydroxychloroquine	S	Unknown	Unk, Once A Day	Not Reported
Hydroxychloroquine	S	Unknown	300 Milligram, Once A Day	Not Reported
Hydroxychloroquine	S	Unknown	300 Milligram, One Every One Hour	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Two Times A Day	Not Reported
Hydroxychloroquine	S	Unknown	Unk, 1 Every 1 Week	Not Reported
Leflunomide	S	Unknown	20 Milligram, Once A Day	Not Reported
Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil	S	Oral	300 Milligram, Once A Day	Not Reported
Plaquenil	S	Unknown	300 Milligram, Once A Day	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	35 Milligram, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Cyclical	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported
Risedronate	C	Unknown	35 Milligram, Every Week	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16227903	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA020634			Unknown	CAN

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

Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Infliximab Pfizer (Unknown)	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	25 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Celebrex	S		Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	1 Dose	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Desoximetasone	S		Unk	Not Reported
	Humira	S		Unk	Not Reported
	Methadone	S		Unk	Not Reported
	Rampril	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Estrogel	C	Unknown	0.6 %, Three Times A Day	Not Reported
	Estrogel	C	Unknown	1.0 Df Qd	Not Reported
	Estradiol	C		Unk, Tid	Not Reported

Calcium	C		500 Milligram, Qd	Not Reported
Xalatan	C	Ophthalmic	50 Microgram, Qd (50 Mcg 0.005% 1 Drop)	Not Reported
Cosopt	C		Unk, 2x/Day	Not Reported
Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
Vitamin D	C		10000 Unit, Weekly	Not Reported
Jamp K20	C		1500 Mg, 1x/Day	Not Reported
Zingiber Officinale	C	Oral	500 Mg, As Needed	Not Reported
Dorzolamide Hcl And Timolol Maleate	C	Unknown	Unk, 2x/Day	Not Reported
Ergocalciferol	C	Unknown	Unk, Weekly	Not Reported
Ergocalciferol	C	Unknown	Unk, Qd	Not Reported
Morphine	C	Unknown	Unk Unk, As Necessary	Not Reported
Potassium Chloride	C	Unknown	1500 Mg, 1x/Day (Qd)	Not Reported
Gravol Ginger	C	Oral	500 Milligram, As Needed	Not Reported
Baclofen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16446297	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2822466-00		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Feeling Abnormal; Insomnia; Pain In Extremity; Peripheral Swelling; Pneumonia; Rheumatoid Factor Increased; Rheumatoid Nodule; Somnolence; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Plaquenil			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16510049	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570129-00		49 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16682901	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-22253		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Liver Function Test Increased; Off Label Use; Palpitations; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Otezla	S	Oral	Unknown	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported
Acetaminophen And Codeine	C	Unknown		Not Reported
Acetaminophen And Codeine	C	Unknown	Unknown	Not Reported
Acetaminophen And Codeine	C	Unknown	Unknown	Not Reported
Amitriptyline Hydrochloride	C	Unknown	Unknown	Not Reported
Aspirin	C	Unknown	Unknown	Not Reported
Baclofen	C	Unknown	Unknown	Not Reported
Betahistine Hydrochloride	C	Unknown	Unknown	Not Reported
Caffeine	C	Unknown	Unknown	Not Reported
Calcium	C	Unknown	Unknown	Not Reported
Clonidine	C	Unknown	Unknown	Not Reported
Clonidine Hydrochloride	C	Unknown	Unknown	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Unknown	Not Reported
Fluticasone Propionate	C	Unknown	Unknown	Not Reported
Folinic Acid	C	Unknown	Unknown	Not Reported
Gabapentin	C	Unknown	Unknown	Not Reported
Hydrochlorothiazide	C	Unknown	Unknown	Not Reported
Losartan	C	Unknown	Unknown	Not Reported
Metoprolol Tartrate	C	Unknown	Unknown	Not Reported
Mometasone Furoate	C	Unknown	Unknown	Not Reported
Naproxen	C	Unknown	Unknown	Not Reported
Naproxen	C	Unknown	Unknown	Not Reported

	Tylenol With Codeine	C	Unknown	Unknown		Not Reported
	Folic Acid	C	Unknown			Not Reported
	Plaquenil	C	Unknown			Not Reported
	Acetaminophen	C	Unknown	Unknown		Not Reported
	Codeine	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16700535	EXPEDITED (15-DAY)		HO, LT, OT	CA-ABBVIE-19K-028-2885154-00		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Obesity; Off	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Triamcinolone Acetonide			S	Intra-articular	Route: Suspension Intra-Articular		Not Reported
	Triamcinolone Acetonide			S				Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S				Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Naproxen			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Naproxen			S	Unknown			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Triamcinolone			S	Unknown			Not Reported
	Triamcinolone			S				Not Reported

Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Wheelchair User	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S			Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S			Not Reported
	Prednisone	S	Oral		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S			Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Gammagard	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)		Not Reported
	Triamcinolone Hexacetonide	S	Other		Not Reported
	Triamcinolone Hexacetonide	S			Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16820459	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3442			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Product Use Issue; Rheumatoid Arthritis; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Gold	S	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16833020	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2933128-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			C				Not Reported
	Plaquenil			C	Oral			Not Reported
	Prednisone			C				Not Reported
	Simponi			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	16878971	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2569757-00		77 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo Hydroxyquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17144108	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-19K-163-2800982-00		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthma; Asthma; Chest Discomfort; Chest X-Ray Abnormal; Fall; Glaucoma; Joint Swelling; Macular Degeneration; Musculoskeletal Disorder; Musculoskeletal Pain; Nausea; Pneumonia; Pyrexia; Respiratory Tract Infection Bacterial; Retinal	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Citrate Free		Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Toxicity; Rib Fracture; Therapeutic Response Shortened; Wheelchair User; White Blood Cell Count Increased	Sulfasalazine	S	Unknown	Not Reported
	Iron	C	Unknown	Not Reported
	Folic	C	Unknown	Not Reported
	Eliquis	C		Not Reported
	Prilosec	C		Not Reported
	Zantac	C		Not Reported
	Losartan	C		Not Reported
	Flexeril	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17153987	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027344			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Morphine Sulfate			S	Unknown	Unk		Not Reported
	Morphine Hydrochloride			S	Unknown	Unk		Not Reported
	Cefixime			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			S	Oral	100 Milligram		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rivotril			S	Unknown	Unk		Not Reported
	Zantac			S	Unknown	Unk		Not Reported
	Zopiclone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17324085	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported

	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17412202	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000692			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pleural Effusion	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17439290	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-011929		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Skin Eruption	Coumadine			S	Oral	Unk		Bristol Myers Squibb
	Innohep			S	Oral	Unk		Not Reported
	Omnipaque			S	Intravenous (not otherwise specified)	55 Milliliter		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Kardegic			S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17530620	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021584			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17549765	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2020-013114		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Atorvastatin			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Aurobindo
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown	Unk		Not Reported

	Rivaroxaban			S	Unknown	Unk,6 Months			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563119	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022177		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Endocervical			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown	2 Dosage Form, Qd		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qwk		Not Reported
	Estradiol			C	Unknown			Not Reported
	Estrogel			C	Unknown	1 Dosage Form, Qd		Not Reported
	Furosemide			C	Unknown	40 Milligram, Qd		Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram, Qd		Not Reported
	Valsartan			C	Unknown	320 Milligram, Qd		Not Reported
	Xalatan			C	Ophthalmic	50 Microgram, Qd		Not Reported
	Zingiber Officinale			C	Oral	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563205	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022138			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Kevzara			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aluminum Acetate			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Benzethonium Chloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Neurontin			C	Unknown	600 Milligram, 3 Every 1 Day		Not Reported
	Premarin			C	Unknown			Not Reported
	Tylenol			C	Unknown	650 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563481	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566876		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Enbrel		S	Subcutaneous		Not Reported
	Hydroxychloroquine		S	Unknown		Not Reported
	Leflunomide		S	Oral		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Methotrexate		S	Oral		Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Methotrexate		S	Subcutaneous	Solution	Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Orencia		S	Subcutaneous		Not Reported
	Prednisone		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown		Not Reported
	Folic Acid		C	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		C			Not Reported
	Simponi		C	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566890			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Solution		Not Reported

Orencia	S	Unknown		Not Reported
Vioxx	S	Unknown		Not Reported
Naproxen	S	Unknown		Not Reported
Leflunomide	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563528	EXPEDITED (15-DAY)		HO, LT, OT	PT-ACCORD-176291		50 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Cardiogenic Shock; Cardiomegaly; Concomitant Disease Aggravated; Dyspnoea Exertional; Dyspnoea Paroxysmal Nocturnal; Electrocardiogram Qrs Complex Abnormal; Heart Sounds Abnormal; Oedema Peripheral; Pericardial Drainage; Pericardial Effusion; Pericardiotomy; Pleural Effusion; Prohormone Brain Natriuretic Peptide Increased; Rales; Serositis	Mycophenolic Acid			S	Unknown	2.5 G, Qd		Accord
	Bosentan			S	Oral	250 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	5 Mg, Qd		Not Reported
	Remodulin Sq			S	Subcutaneous	0.046 Mg, Q1hour		Not Reported
	Riociguat			C	Unknown	6 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563805	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022560			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Daily Activities; Rheumatoid Arthritis	Arava	S	Unknown		Not Reported
	Celecoxib	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Prednisone	C	Unknown	2 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17563950	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571269			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564021	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202003001710			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abdominal Tenderness; Chest Pain; Cough; Decreased Appetite; Dyspnoea; Herpes Simplex Hepatitis; Lethargy; Lymphopenia; Musculoskeletal Chest Pain; Nausea; Somnolence; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Mg, Bid, Tablet		Concordia
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Metronidazole			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564032	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP008890			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Intolerance; Maculopathy; Pneumonia; Product Use Issue; Visual Impairment	Leflunomide			S	Oral	10 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Methotrexate			C	Subcutaneous	20 Mg, Unk		Not Reported
	Sulfasalazine			C	Unknown	500 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564060	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573629-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pancreatitis; Product Use Issue	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported
	Hydromorph Contin			C				Not Reported

	Lyrica			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564141	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1432			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cystitis; Hepatitis B Reactivation; Inflammation; Malaise; Stomatitis; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564207	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022599			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564413	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566946			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17564456	EXPEDITED (15-DAY)		OT	CA-SA-2020SA067248			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Diarrhoea; Diarrhoea; Nausea; Renal Failure	Leflunomide			S		20 Mg, Qd		Sanofi
	Plaquenil			S		400 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17565635	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022535		43 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection;	Orencia			S	Unknown	200 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Arava	S	Oral	10 Milligram	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Unk	Not Reported
	Prednisone	S	Unknown	20 Nanogram	Not Reported
	Rituximab	S	Intravenous drip	2 Gram	Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Unk	Not Reported
	Risedronate Sodium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17566118	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR-APL-2019-095261		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In	Alendronic Acid			S	Unknown	70 Milligram, 4 Every 1 Week		Aurobindo
	Apo-Alendronate			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Ibuprofen			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Oral	500 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Methotrexate			S	Oral	10 Milligram, Every Week		Not Reported
	Apo-Methotrexate			S	Subcutaneous	12 Milligram, Every Week		Not Reported
	Apo-Methotrexate			S	Subcutaneous	10 Milligram, Every Week		Not Reported
	Apo-Methotrexate			S	Subcutaneous	12.5 Milligram, Every Week		Not Reported
	Apo-Methotrexate			S	Subcutaneous	17.5 Milligram, Every Week		Not Reported

Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Apo-Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Subcutaneous	70 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Unknown	17.5 Milligram,Four In One Week	Not Reported
	Apo-Methotrexate	S	Unknown	12 Milligram,Four In One Week	Not Reported
	Apo-Methotrexate	S	Unknown	10 Milligram, Four In One Week	Not Reported
	Apo-Methotrexate	S	Unknown	12.5 Milligram,Four In One Week	Not Reported
	Apremilast	S	Unknown	60 Milligram, Two Times A Day	Not Reported
	Apremilast	S			Not Reported
	Apremilast	S			Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram,Two Every One Week	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Ibuprofen	S	Oral	600 Milligram	Not Reported
	Ibuprofen	S	Unknown	600 Milligram, Once A Day	Not Reported
	Ibuprofen	S	Unknown	Unk, Once A Day	Not Reported
	Infliximab	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Motrin	S	Oral	600 Mg, Qd	Not Reported
	Motrin	S	Oral	Unk Unk, Qd	Not Reported

Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S			Not Reported
Otezla	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	1000 Mg, Bid	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram,One Every Month	Not Reported
Tocilizumab	S	Unknown	680 Milligram,One Every Four Week	Not Reported
Alendronate	C	Unknown	70 Mg, Q.Wk.	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Colchicine	C	Oral	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Humira	C	Unknown	40 Milligram	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram,Four Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Four Every 1 Week	Not Reported
Methotrexate	S	Unknown	10 Milligram,Four Every 1 Week	Not Reported

	Methotrexate	S	Unknown	12.5 Milligram,Four Every 1 Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram,Four Every 1 Week	Not Reported
	Methotrexate	S	Unknown	70 Milligram, Every Week	Not Reported
	Mogadon	C	Oral	5 Milligram	Not Reported
	Nitrazepam	C	Unknown	5 Milligram	Not Reported
	Oxycodone	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	20 Milligram	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Tocilizumab	C	Unknown	680 Milligram	Not Reported
	Tocilizumab	C	Unknown	360 Milligram	Not Reported
	Uloric	C	Unknown	80 Milligram, Two Times A Day	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17566974	EXPEDITED (15-DAY)		OT	NVSC2020CA079201			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Eye Disorder; Off Label Use; Psoriasis; Rash; Rheumatoid Arthritis; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hidroxicloroquina			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Arava	C	Unknown	Unk		Not Reported
Desvenlafaxine Succinate	C	Unknown	Unk		Not Reported
Leflunomide	C	Oral	20 Mg, Qd		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Quetiapine Fumarate	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567557	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022569		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Vitamin D 3			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567657	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022553		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug	Orencia			S	Unknown			Bristol Myers Squibb

Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	50.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Oral	5.0 Milligram 2 Every 1 Days	Not Reported
	Xeljanz	S	Unknown	5.0 Milligram 2 Every 1 Days	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Hydromorphone	C	Unknown		Not Reported
	Remicade	C	Intravenous (not otherwise specified)		Not Reported
	Synthroid	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567671	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA078923			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Otezla	S	Oral	Unk		Not Reported
Simponi	S	Subcutaneous	Unk (Solution)		Not Reported
Stelara	S	Subcutaneous	Unk (Solution)		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567912	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022607		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	160 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17567934	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		35 YR	Female	CAN

BMS-2020-022780

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Feeling Abnormal; Insomnia; Pain In Extremity; Peripheral Swelling; Pneumonia; Rheumatoid Factor Increased; Rheumatoid Nodule; Somnolence; Weight Increased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17568087	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022579		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pancreatitis; Product Use Issue	Orencia			S	Unknown			Bristol Myers Squibb
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	25.0 Milligram		Not Reported
	Plaquenil S			S	Unknown	200.0 Milligram, Qwk		Not Reported
	Amitriptyline			C	Unknown			Not Reported
	Hydromorph Contin			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17568106	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022615		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Rhinorrhoea; Skin Mass	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25.0 Milligram		Not Reported
	Xeljanz			S	Oral	5.0 Milligram 2 Every 1 Days		Not Reported
	Xeljanz			S	Oral	5.0 Milligram 1 Every 1 Days		Not Reported
	Morphine			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17568283	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA068487			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Drug Ineffective	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S	Oral	20 Mg		Sanofi
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	17.5 Mg		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2020	17568289	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068881			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S		200 Mg, Bid		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		25 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	15622307	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557499-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo Hydroxyquine	S	Unknown	Not Reported
	Sulfasalazine	C		Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Bupropion	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	15624381	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556781-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Apo-Leflunomide	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Meloxicam	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C		Not Reported
	Prednisolone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	15625734	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557153-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo Prednison			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	15663999	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570464-00		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Itravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Ntravenous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Rituximab			S				Not Reported

	Lyrica	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	15683294	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573840-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Diclofenac			C				Not Reported
	Depo-Medrol			C	Intra-arterial			Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Pantoprazole Magnesium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	16718423	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2892907-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	17563703	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3328160-00		59 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Headache; Pneumothorax	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Tylenol			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	17567968	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2020025732			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Clopidogrel			S	Unknown	Unk		Macleods
	Atorvastatin			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	Unk		Not Reported

	Hydroxychloroquine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Mar-2020	17572435	DIRECT					39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness Unilateral	Hydroxychloroquine	Y		S			6 MTH	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	13186699	EXPEDITED (15-DAY)		OT	CA-ROCHE-1888735		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Rheumatoid Arthritis; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	14906435	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028-1678150-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Cimzia	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Tylenol	S	Unknown	Dosage Maintained	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Methotrexate	C			Not Reported
	Meloxicam	C	Unknown		Not Reported
	Synthroid	C			Not Reported
	Tylenol No. 3	C			Not Reported
	Celebrex	C			Not Reported
	Acetaminophen And Codeine Phosphate	C			Not Reported
	Hydromorphone Hcl	C			Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	14921809	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043962		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb

Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Gold	S	Unknown		Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
	Humira	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	40 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
	Remicade	S	Unknown	200 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Anakinra	C	Unknown	100 Mg, Unk	Not Reported
	Ativan	C	Unknown	1 Gram, Qd	Not Reported
	Ativan	C	Unknown	1 Milligram	Not Reported
	Codeine	C	Unknown		Not Reported
	Desoximetasone	C	Oral	Unk	Not Reported
	Desoximetasone	C	Intramuscular	Unk	Not Reported
	Desoximetasone	C	Intra-articular	Unk	Not Reported
	Dexamethasone	C	Unknown		Not Reported
	Dilaudid	C	Unknown	4 Milligram, Qid	Not Reported

Dilaudid	C	Unknown	4 Milligram, Qd	Not Reported
Diphenhydramine	C	Unknown		Not Reported
Enablex [Darifenacin]	C	Unknown		Not Reported
Enablex [Darifenacin]	C	Unknown		Not Reported
Hydromorphone	C	Unknown		Not Reported
Kadian	C	Unknown		Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	40 Mg, Unk	Not Reported
Lasix [Furosemide]	C	Unknown	40 Milligram, Tid	Not Reported
Loperamide	C	Unknown	2 Milligram, Bid	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown		Not Reported
Omnaris	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported
Pantoprazole Sodium	C	Unknown		Not Reported
Restasis	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Trimethoprim	C	Unknown		Not Reported
Urispas	C	Unknown	200 Milligram	Not Reported
Vagifem	C	Vaginal		Not Reported
Dyclonine Hydrochloride	C	Unknown	Unk	Not Reported
Benadryl Cold	C	Unknown		Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Unk, Prn	Not Reported
Morphine Sulphate	C	Unknown		Not Reported
Plantago Ovata	C	Unknown		Not Reported
Rituximab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	15328456	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175439			Female	CAN

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

Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	15683363	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574500-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatic Disorder; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Aspirin			C				Not Reported
	Cymbalta			C				Not Reported
	Hydromorphone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17530404	EXPEDITED (15-DAY)		OT	NVSC2020CA070217			Female	CAN

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

C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Cosentyx		S	Unknown	Unk	Novartis
	Methotrexate		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Arava		S	Unknown	Unk	Not Reported
	Cimzia		S	Subcutaneous	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Otezla		S	Unknown	Unk	Not Reported
	Otezla		S	Oral	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Stelara		S	Subcutaneous	Unk	Not Reported
	Stelara		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17533813	EXPEDITED (15-DAY)		OT	NVSC2020CA069732		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Orencia	S	Unknown	Unk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	1 Df	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	50 Mg	Not Reported
	Zingiber Officinale	C	Oral	500 Mg	Not Reported
	Zingiber Officinale	C	Unknown	500 Mg	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xalatan	C	Ophthalmic	50 Mg, Qd	Not Reported
	Valsartan	C	Unknown	320 Mg, Qd	Not Reported
	Potassium Chloride	C	Unknown	1500 Mg, Qd	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Jamp K20	C	Unknown	1500 Mg, Qd	Not Reported
	Gravol	C	Unknown	500 Mg	Not Reported
	Furosemide	C	Unknown	40 Mg, Qd	Not Reported
	Estrogel	C	Unknown	1 Df, Qd	Not Reported
	Estrogel	C	Unknown	0.6 % Tid	Not Reported
	Estradiol	C	Unknown	0.6 % Tid	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qw	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qw	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Qd	Not Reported

	Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unk Unk, Bid	Not Reported
	Calcium	C	Unknown	500 Mg, Qd	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Tofacitinib Citrate	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17542710	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA071289		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Naprosyn			C	Unknown			Not Reported
	Erythromycine			C	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17545270	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020929			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Somnolence; Visual Impairment	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported
	Tylenol			S	Unknown			Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Mar-2020	17569409	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022556		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase	Orencia			S	Unknown			Bristol Myers Squibb

Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Actemra	S	Unknown	680 Milligram	Not Reported
	Actemra	S	Unknown	360 Milligram 1 Every 1 Months	Not Reported
	Alendronate	S	Unknown	70 Milligram 1 Every 1 Weeks	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	12.0 Milligram 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	10.0 Milligram 1 Every 1 Weeks	Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Unknown	1000 Milligram 2 Every 1 Days	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Milligram 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Oral	10 Milligram 1 Every 1 Weeks	Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	11865597	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2012292491		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Enbrel			S				Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day (Q12h)		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	10 Mg, Daily (2 In 1 Day)		Pfizer
	Xeljanz			S		12.5 Mg, Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 1x/Day Qd (1 Every 1 Day)		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Aleve			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Oral	5 Mg, 2x/Day (Q12h)		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Hydroxychloroquine Sulfate	S		40 Mg, Unk	Not Reported
Apo-Hydroxyquine	S		400 Milligram	Not Reported
Prednisone Acetate	S	Unknown	Unk	Not Reported
Naproxen	S		Unk	Not Reported
Leflunomide	S	Unknown	Unk Unk, Cyclical (1 Every Two Days)	Not Reported
Leflunomide	S	Unknown	Unk Unk, Bid	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Mg, Unk	Not Reported
Folic Acid	C	Subcutaneous	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Hcq	C		Unk	Not Reported
Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	2 Df, Qd	Not Reported
Insulin	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	2 Dosage Form, Bid	Not Reported
Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	20 Milligram	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	12769492	EXPEDITED (15-DAY)		CA, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076352			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Orencia			S	Endocervical	Unk		Bristol Myers Squibb
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	Unk Unk, 2 Times/Wk		Not Reported
	Enbrel			S	Unknown	Unk, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Naproxen			S	Oral	500 Mg, Bid		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Vioxx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Naprosyn [Naproxen]			S	Oral	500 Milligram, Bid		Not Reported
	Naprosyn [Naproxen]			S	Unknown	500 Milligram, 2 Times/Wk		Not Reported
	Naproxen Sodium			S	Oral	500.0 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Leflunomide			C	Unknown	10 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	13147266	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005239		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Off Label Use; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Toradol			S	Unknown			Not Reported
	Celecoxib			S	Oral	200 Milligram, Bid		Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	13251292	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP006546		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug	Hydroxychloroquine			S	Oral	400 Mg, Bid		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown			Not Reported

Intolerance; Dyspnoea; Hernia; Joint Destruction; Nausea; Rheumatoid Arthritis; Stoma Complication	Apo-Prednisone		S	Unknown	Unk	Apotex
	Apo-Leflunomide		S	Unknown	Unk	Apotex
	Actemra		S	Unknown		Not Reported
	Celebrex		S	Oral	200 Mg, Bid	Not Reported
	Methotrexate Sodium		S	Subcutaneous	0.8 Ml, Q.Wk.	Not Reported
	Sulfasalazine		S	Oral	1000 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	13251533	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006675		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Apo-Leflunomide			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Mefenamic Acid			C	Unknown			Not Reported
	Prednisone			C	Oral	6 Mg, Qd		Not Reported
	Prednisone			C	Oral	10 Mg, Qd		Not Reported

	Tylenol /00020001/	C	Unknown		Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	14235040	EXPEDITED (15-DAY)		DE, OT	CA-APOTEX-2017AP021690		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Hypersensitivity; Drug Ineffective; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Adalimumab			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Adalimumab			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Qid		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	50 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	14238496	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021706			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported

Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Q.Wk.	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Varenicline Tartrate	S	Oral	1 Df, Qd	Not Reported
Varenicline Tartrate	S			Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
Esomeprazole Magnesium W/Naproxen	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Rosuvastatin Calcium	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Valtrex	C	Unknown	Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	14239514	EXPEDITED (15-DAY)		HO, OT	CA-PURDUE PHARMA-CAN-2016-0006553		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Dry Eye;	Oxycontin			S	Unknown	Unk		Purdue
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Monthly		Not Reported
	Arava			S	Oral	20 Mg, Daily		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Weekly		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Gabapentin			S	Oral	100 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk Unk, Weekly		Not Reported

Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Skin Lesion; Sleep Disorder; Treatment Failure	Myochrysine	S	Intramuscular	50 Mg, 1 Every 3 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 3 Weeks	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Daily	Not Reported
	Sulfasalasin	S	Oral	2.5 G, Daily	Not Reported
	Acetaminophen W/Oxycodone	C		1 Df, Prn	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported
	Actonel	C	Unknown	36 Mg, Weekly	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
	Tocopherol	C	Unknown	Unk	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Daily	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	400 Iu, Daily	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Daily	Not Reported
	Esomeprazole Magnesium	C	Unknown	40 Mg, Bid	Not Reported
	Ferrous Gluconate	C	Unknown	300 Mg, Daily	Not Reported
	Loperamide Hcl	C	Unknown	2.5 Mg, Unk	Not Reported
	Nasonex	C	Nasal	2 Df, Bid	Not Reported
	Nicotinamide	C	Unknown	Unk	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Mg, Unk	Not Reported
	Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
	Pantoprazole	C	Unknown	40 Mg, Daily	Not Reported
	Prednisone	C	Unknown	5 Mg, Daily	Not Reported
	Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported

	Sodium	C	Unknown	Unk	Not Reported
	Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Mg, Daily	Not Reported
	Tylenol /00020001/	C	Oral	1000 Mg, Daily	Not Reported
	Vitamin A /00056001/	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Vitamin B12 /00056201/	C	Unknown	Unk	Not Reported
	Ferrous Fumarate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Sodium Ascorbate	C	Unknown	Unk	Not Reported
	Thiamine Mononitrate	C	Unknown	Unk	Not Reported
	Vitamin C /00008001/	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	14757583	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009592			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Intolerance; Impaired Work Ability; Middle Insomnia; Rheumatoid Arthritis; Rheumatoid Nodule; Synovitis; White Blood Cell Count Decreased	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Penicillin			S	Unknown	Unk		Apotex
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Aspirin /00002701/			S	Unknown	Unk		Not Reported
	Penicillin G /00000901/			S	Unknown	Unk		Not Reported
	Penicillin G Potassium			S	Unknown	Unk		Not Reported
	Penicillin G Procaine			S	Unknown	Unk		Not Reported

	Pregabalin		C	Unknown	Unk	Not Reported
	Tylenol /00020001/		C	Unknown	Unk	Not Reported
	Acetaminophen		C	Unknown	Unk	Not Reported
	Acetaminophen And Codeine Phosphate		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	15619609	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555410-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	11 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	15623842	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557025-00		57 YR	Female	CAN

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

Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Toe Amputation; Victim Of Crime	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Ophthalmic	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Restasis	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Vitamins Nos	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	15629783	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557408-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Malaise; Mood Swings; Musculoskeletal Stiffness;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Vomiting	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Indometacin	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Cymbalta	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	16357705	EXPEDITED (15-DAY)			CA-ORION CORPORATION ORION PHARMA-TREX2019-1532			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Hyperhidrosis; Inappropriate Schedule Of Product Administration; Nausea; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Estradot			S	Transdermal			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	16473931	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Inflammation; Joint Stiffness; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Kevzara			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Tocilizumab	S	Unknown	Not Reported
	Abatacept	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Adalimumab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rabeprazole Sodium	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	16857402	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574079-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Contraindicated Product Administered; Rash; Treatment Failure; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17529190	EXPEDITED (15-DAY)		OT	NVSC2020AU065740			Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Eye Movement Disorder; Mobility Decreased; Scleroderma	Tacrolimus			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown	10 Mg, Unknown		Not Reported
	Prednisone			S	Unknown	Up To 50 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	0.25 Mg/Kg, Unknown		Not Reported
	Prednisolone			S	Unknown	1 Mg/Kg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569440	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023131			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569450	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023149			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Endocervical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569480	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001670			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Hepatic Enzyme Increased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	1000 Mg, Bid		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Gliclazide			C		Unk		Not Reported
	Vimovo			C		Unk		Not Reported
	Rabeprazole			C		Unk		Not Reported
	Mr			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569650	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022575		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	680 Milligram, Q4wk		Not Reported
	Actemra			S	Unknown	360 Milligram, Qwk		Not Reported
	Alendronate			S	Unknown	70 Milligram, Qwk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Qmo		Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Ciclosporin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569669	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023123			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Orencia			S	Endocervical			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	2 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569671	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022648		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569754	EXPEDITED (15-DAY)		HO	CA-ROCHE-2565726		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569843	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022714		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Nausea;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Qmo		Not Reported
	Arava			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	100 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported

Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Methotrexate	S	Subcutaneous	Unk, Qwk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Q3wk	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	2.5 Gram, Qd	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Qd	Not Reported
	Ergocalciferol	C	Unknown	400 International Unit, Qd	Not Reported
	Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
	Ferrous Fumarate	C	Unknown	300 Milligram	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Hydroxocobalamin	C	Unknown	Unk	Not Reported
	Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
	Nasonex	C	Unknown	2 Dosage Form, Bid	Not Reported
	Nicotinamide	C	Unknown	Unk	Not Reported
	Nortriptyline Hydrochloride	C	Oral	40 Milligram, Qd	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram	Not Reported
	Prednisone	C	Unknown	5 Gbq 1 Every 1 Day	Not Reported
	Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
	Riboflavin	C	Unknown	Unk	Not Reported
	Risedronate Sodium	C	Unknown	36 Milligram, Qd	Not Reported
	Sodium Ascorbate	C	Unknown	Unk	Not Reported
	Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
	Thiamine Mononitrate	C	Unknown	Unk	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Milligram, Qd	Not Reported
	Tylenol	C	Unknown	1000 Milligram, Qd	Not Reported

Vitamin A [Retinol]	C	Unknown	Unk		Not Reported
Vitamin C [Ascorbic Acid]	C	Unknown	Unk		Not Reported
Vitamin D3	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569878	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2020-1453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Drug Ineffective	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17569879	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1451			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Atorvastatin Calcium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Alprazolam			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported
	Pantoloc			C	Unknown			Not Reported

	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570139	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201611-005804			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Unk		Concordia
	Arava			S	Oral	10 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Every Other Week		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	20 Mg (Tablet)		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Endocervical	20 Mg, Qd		Not Reported
	Prednisone			S	Endocervical	20 Mg, Qd		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2 G,Qcy; Iv Nos		Not Reported
	Rituxan			S	Unknown	2 Unk, Qcy; Unknown		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	2 G, Q6m; Iv Nos		Not Reported

	Etanercept	S	50 Mg, Weekly	Not Reported
	Methotrexate	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570142	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202001000092			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Dry Eye; Dry Mouth; Fatigue; Finger Deformity; Impaired Driving Ability; Macular Degeneration; Pain In Extremity; Rheumatoid Arthritis; Rheumatoid Nodule; Somnolence	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Levothyroxin			C		Unk		Not Reported
	Raloxifene			C		Unk		Not Reported
	Lidoderm			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570259	EXPEDITED (15-DAY)		LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023559			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use;	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	Unk Unk, Qd		Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	3 Milligram, Bid		Not Reported
	Enbrel			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported

Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral	Unk Unk, Qd	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Triamcinolone	S	Intra-articular		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570302	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068781			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease; Rash	Leflunomide			S		10 Mg		Sanofi
	Plaquenil			S	Oral	200 Mg, Q12h		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570308	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068804			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Interstitial Lung Disease	Leflunomide			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	400 Mg		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570311	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068793			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered;	Leflunomide			S				Sanofi

Hepatotoxicity; Rash; Treatment Failure	Hydroxychloroquine Sulfate	S		1 Df		Sanofi
	Adalimumab	S	Subcutaneous			Not Reported
	Azathioprine	S		1 Df		Not Reported
	Orencia	S	Subcutaneous	125 Df, Qw		Not Reported
	Methotrexate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570367	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023442		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Other	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570370	EXPEDITED (15-DAY)		HO, OT	CN-LUPIN PHARMACEUTICALS INC.-2020-01473		52 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nocardiosis	Hydroxychloroquine			S	Unknown	0.2 Gram, Bid		Lupin
	Prednisone			S	Unknown	60 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	50 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	20 Milligram, Qd In 2 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570449	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2500975-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Ineffective; Drug Intolerance; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Lipoma; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Osteoporosis; Pain; Pain In Extremity; Pain In Jaw; Peripheral Coldness; Platelet Count Decreased; Rhinorrhoea; Skin Mass	Xeljanz		S	Oral		Not Reported
	Xeljanz		S	Oral		Not Reported
	Xeljanz		S	Oral		Not Reported
	Synthetic Morphine		C	Unknown	Unknown Dose 1 Or 2	Not Reported
	Tylenol		C		Unknown Hs	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570483	EXPEDITED (15-DAY)		OT	CA-ROCHE-2570439		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570489	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571132		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Drug Ineffective; Joint Swelling; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Osteomyelitis; Pain; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Nodule; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz Xr			C	Oral			Not Reported
	Xeljanz Xr			C	Unknown			Not Reported
	Xeljanz Xr			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570607	EXPEDITED (15-DAY)		OT	NVSC2020CA077910		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	6.78 Mg/Kg (Cumulative Dose 1.24 Kg)		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570792	EXPEDITED (15-DAY)		OT	NVSC2020CA079412		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicaide			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17570987	NON-EXPEDITED			US-PFIZER INC-2020121578		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer

	Methotrexate Sodium	S		Unk	Pfizer
	Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk (0, 2, 6 Wks, Then Every 8 Wks.)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk (Every 8 Weeks)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk (Every 7 Weeks)	Not Reported
	Humira	S		Unk	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Otrexup	S		Unk	Not Reported
	Prednisone	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17571152	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020118213			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate Sodium			S	Oral			Pfizer
	Methotrexate Sodium			S	Other	Unk		Pfizer
	Enbrel			S	Unknown			Pfizer
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17571244	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020118892			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S		20 Mg		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		300 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17571456	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA079635		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Voltaren Sr			S	Oral	75 Mg, Bid		Novartis
	Apo Diclo			S	Oral	75 Mg, Bid		Not Reported
	Apo Lisinopril			S	Oral			Not Reported
	Diclofenac			S	Oral	75 Mg, Bid		Not Reported
	Diclofenac			S	Oral	75 Mg, Bid		Not Reported
	Diclofenac Potassium			S	Oral	75 Mg, Prn		Novartis
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Not Reported
	Lisinopril			S	Unknown			Not Reported
	Lisinopril Dihydrate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Pantoprazol			S	Unknown			Not Reported
	Pantoprazol			S	Oral	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported
	Synthroid			S	Oral			Not Reported
	Tecta			S	Oral			Not Reported
	Xeljanz			S	Oral	10 Mg, Qd		Not Reported
	Gold			C	Unknown			Not Reported
	Depo-Medrol			C	Intramuscular			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17572087	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069054			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Etanercept			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17572198	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024000			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ilaris	S	Intravenous (not otherwise specified)		Not Reported
	Ilaris	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous		Not Reported
	Ilaris	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17572243	EXPEDITED (15-DAY)		OT	US-SA-2020SA071865			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium; Drug Interaction; Retinopathy; Visual Field Defect	Hydroxychloroquine			S				Sanofi
	Docetaxel			S				Sanofi
	Anastrozole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17572378	EXPEDITED (15-DAY)		OT	NVSC2020CA079465			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573060	EXPEDITED (15-DAY)		HO, LT, OT	PT-MYLANLABS-2020M1029307			Unknown	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Cardiogenic Shock; Serositis	Mycophenolate Mofetil			S	Unknown	2.5 Gram		Not Reported
	Bosentan			S	Unknown	250 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Mylan
	Prednisolone			S	Unknown	5 Milligram		Mylan
	Remodulin			S	Subcutaneous	0.046 Mg/H, Continuing		Mylan
	Riociguat			C	Unknown	6 Milligram		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573076	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA079709		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Delirium; Dislocation Of Vertebra; Drug	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Off Label Use; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Disorder; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Leflunomide		S	Unknown	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Unknown	500 Mg, Bid	Not Reported
	Naprosyn		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573103	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1031278		13 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Hydroxychloroquine			S	Unknown	For 6 Weeks		Not Reported
	Prednisone			S	Oral	1 Milligram/Kilogram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573142	EXPEDITED (15-DAY)		OT	NVSC2020CA079502		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Voltaren			S	Unknown	Unk		Novartis
	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Diclofenac			S	Unknown	Unk		Novartis
	Diclofenac Potassium			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Enbrel	S	Subcutaneous	Unk		Not Reported
Apo-Diclofenac	S	Unknown	Unk		Not Reported
Desoximetasone	S	Unknown	Unk		Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573170	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023021		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Q2wk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk, Q6wk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573206	EXPEDITED (15-DAY)		OT	NVSC2020CA079493		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment	Voltaren Sr			S	Unknown	75 Mg, Prn		Novartis
	Folic Acid			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported

Failure	Sulfasalazine		S	Unknown	500 Mg, Qd	Not Reported
	Synthroid		S	Unknown	Unk	Not Reported
	Tecta		S	Oral	Unk	Not Reported
	Xeljanz		S	Unknown	5 Mg, Bid	Not Reported
	Depo-Medrol		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573227	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023154			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Subcutaneous	1 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Topicort Lp			S	Topical	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573297	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023109		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported
	Prednisone			C	Unknown	30 Milligram, Qd		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17573405	NON-EXPEDITED			NVSC2020US082232			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychotic Disorder	Hydroxychloroquine			S	Oral	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2020	17581632	DIRECT					66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Purpura	Plaquenil			S	Oral			Not Reported
	Tirosint			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	13058057	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015766		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	13251448	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006660			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug	Apo-Hydroxyquine			S	Unknown			Apotex
	Apo-Hydroxyquine			S				Apotex

Intolerance; Off Label Use; Rheumatoid Arthritis	Apo-Cyclosporine	S	Unknown		Apotex
	Apo-Cyclosporine	S			Apotex
	Apo-Azathioprine	S	Unknown	Unk	Not Reported
	Apo-Azathioprine	S			Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S			Apotex
	Cyclosporine	S	Unknown	Unk	Apotex
	Cyclosporine	S			Apotex
	Azathioprine	S	Unknown	Unk	Apotex
	Azathioprine	S			Apotex
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
	Actemra	S	Unknown	640 Mg, Q.Wk.	Not Reported
	Arava	S	Oral		Not Reported
	Arava	S			Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Q.Wk.	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
	Humira	S	Unknown	400 Mg, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
	Imuran /00001501/	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported

	Sulfasalazine		S	Unknown		Not Reported
	Sulfasalazine		S			Not Reported
	Tocilizumab		S	Unknown	640 Mg, Q.Wk.	Not Reported
	Tocilizumab		S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	14498265	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007254			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Off Label Use; Thyroid Disorder	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	14502886	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007063		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disability; Disease Recurrence; Drug Ineffective; Dyspnoea; Impaired Work Ability; Infection; Insomnia; Joint Lock; Joint Swelling; Limb	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qd		Not Reported

Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Peripheral Swelling; Physical Disability; Rash; Rheumatoid Arthritis; Skin Mass; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Decreased; Therapy Non-Responder	Arava	S	Oral	200 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qmo	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200 Milligram, Qd	Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone Acetate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Tofacitinib Citrate	S	Oral	5 Milligram,2every1day	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Apo-Hydroxyquine	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2 Gram, Q6mo	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Actonel	C	Unknown		Not Reported
	Sulfasalazine	C	Oral	Unk	Not Reported
	Sulfasalazine	C	Oral	500 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15629234	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2558776-00		21 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pneumonia; Rash; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Dose Decreased		Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Intravenous Drip		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported

	Doxycycline	S	Unknown	Not Reported
	Doxycycline Hyclate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Abatacept	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Acetaminophen/Codeine Phosphate	C	Unknown	Not Reported
	Meloxicam	C		Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Synthroid	C	Unknown	Not Reported
	Codeine Phosphate	C		Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Not Reported
	Celebrex	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15632850	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105426		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported

Methotrexate	S	Oral	Unk		Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram		Not Reported
Xeljanz	C	Unknown	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15681461	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2575030-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported

	Remicade	C	Intravenous (not otherwise specified)		Not Reported
	Orencia	C			Not Reported
	Acetylsalicylic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15689905	EXPEDITED (15-DAY)		HO, OT	CA-SAKK-2018SA324553AA		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Triamcinolone Acetonide			S				Sanofi
	Actemra			S	Intravenous (not otherwise specified)	280 Mg		Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Anakinra			S		50 Mg, Qd		Not Reported
	Humira Ac			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qw		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15707284	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2584423-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfasalazine	C		Not Reported
	Wellbutrin	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	15712957	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588343-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

	Certolizumab Pegol		S	Unknown	Not Reported
	Azathioprine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	16079901	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-05867			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Triamcinolone			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Actemra	S	Intravenous (not otherwise specified)		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Gamastan	S	Intravenous (not otherwise specified)	Liquid Intramuscular	Not Reported
Humira	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Naproxen Sodium	S	Unknown	Unknown	Not Reported
Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown.	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unknown, Suspension Intra-Articular	Not Reported
Triamcinolone Hexacetonide	S	Intra-articular	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	16211049	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2017SA020214		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Diarrhoea; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis	Hydroxychloroquine			S	Oral	5 Mg/Kg,Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Human Immunoglobulins			S	Intravenous (not otherwise specified)	70 G,Unk		Not Reported
	Human Immunoglobulins			S	Intravenous (not otherwise specified)	70 G,Unk		Not Reported
	Human Immunoglobulins			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2,Qow		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Qw		Not Reported
	Naproxen			S	Unknown	Unk Unk,Unk		Not Reported

Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Prednisone	S	Oral	5 Mg,Bid	Not Reported
	Prednisone	S	Oral	3 Mg,Bid	Not Reported
	Prednisone	S	Unknown	1.3 Mg, Bid	Not Reported
	Isoniazid/Rifampicin	S	Intravenous (not otherwise specified)	Unk	Sanofi
	Sulfasalazine	S	Oral	250 Mg,Qd	Not Reported
	Adalimumab	S	Unknown	Unk Unk,Unk	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	250 Mg,Qm	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg,Qow	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qw	Not Reported
	Anakinra	S	Subcutaneous	50 Mg,Qd	Not Reported
	Anakinra	S	Subcutaneous	50 Unk	Not Reported
	Etanercept	S	Subcutaneous	25 Mg,Qw	Not Reported
	Etanercept	S	Subcutaneous	12.5 Mg,Qw	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg,Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg,Unk	Not Reported
	Triamcinolone	S	Unknown	Unk Unk,Unk	Not Reported
	Triamcinolone	S	Unknown	Unk Unk,Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg,Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Mg,Qw	Not Reported
	Tocilizumab	S		250 Mg, Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qcy (Every 2 Weel)	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Folic Acid	C			Not Reported
	Triamcinolone Hexacetonide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	16778722	EXPEDITED (15-DAY)		HO, OT	CA-ADVANZ PHARMA-GSH201706-003601			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Pruritus; Rash; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis;	Hydroxychloroquine			S	Oral	Unk		Concordia
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Actemra			S	Unknown	680 Mg, Monthly		Not Reported
	Actemra			S	Unknown	360 Mg, Monthly		Not Reported
	Actemra			S	Unknown	380 Mg, Unknown		Not Reported
	Actemra			S	Unknown	360 Mg, Monthly		Not Reported
	Alendronate Sodium			S	Unknown	70 Mg, Weekly		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Freq: 2 X 1 Week		Not Reported
	Enbrel			S	Unknown	50 Mg, Freq: 2 X 1 Week, Biw		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	40 Mg, Freq: 1 X 2 Weeks, Qow		Not Reported
	Humira			S		40 Unk, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg Qow		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Freq: Unk X 1 Weeks		Not Reported
	Methotrexate			S	Oral	10 Mg, Freq: Unk X 1 Weeks		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Freq: Unk X 1		Not Reported

Skin Ulcer; Therapeutic Response Decreased; Ulcer				Weeks	
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Freq: Unk X 1 Weeks	Not Reported
	Methotrexate	S	Unknown	12 Mg, Freq: Unk X 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Freq: Unk X 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg Q4w	Not Reported
	Methotrexate	S	Unknown	12.5 Unk	Not Reported
	Methotrexate	S	Unknown	12 Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Weekly	Not Reported
	Methotrexate	S	Oral	10 Mg Q4w	Not Reported
	Methotrexate	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Weekly	Not Reported
	Methotrexate	S	Oral	10 Mg Q4w	Not Reported
	Methotrexate	S	Unknown	12 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	15.5 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	12 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	70 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	17.5 Mg, Weekly	Not Reported

Methotrexate	S	Unknown	15 Mg Q4w	Not Reported
Methotrexate	S	Unknown	12 Mg Q4w	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg Q4w	Not Reported
Methotrexate	S	Unknown	17 Unk	Not Reported
Methotrexate	S	Unknown	12.5 Unk, Q4w	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	780 Mg, Unknown	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk, Powder And Solvent For Intravesical Suspension	Not Reported
Remicade	S	Unknown	, Powder And Solvent For Intravesical Suspensionunk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Sulfasalazine	S	Unknown	Unk Mg	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Monthly	Not Reported
Myochrysine	S	Parenteral	50 Mg, Monthly	Not Reported
Methotrexate Sodium	S	Oral	10 Mg, Freq: 1 X 2 Weeks, Qow	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Weekly	Not Reported
Rituximab	S	Unknown	1000 Mg, Bid	Not Reported
Tocilizumab	S	Unknown	680 Mg Q4w	Not Reported
Ciclosporin	C		Unk	Not Reported

	Prednisolone	C			Not Reported
	Prednisone	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Xeljanz	C			Not Reported
	Alendronate Sodium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	16836959	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27185		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported

Cimzia	S	Subcutaneous		Not Reported
Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
Cimzia	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Gold	S	Unknown	Unknown	Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	Unknown	Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Imuran	S	Unknown	Unknown	Not Reported
Lyrica	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous	Unknown	Not Reported
Methotrexate	S	Oral	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Unknown	Not Reported
	Piroxicam	C	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	16977712	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201910001380			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Neutropenia; Pain In Extremity; Rash; White Blood Cell Count Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	Unk, Weekly		Not Reported
	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Xeljanz			C		Unk		Not Reported
	Flurbiprofen			C		Unk		Not Reported
	Tylenol			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Prevacid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17404137	EXPEDITED (15-DAY)		CA, HO, OT	NVSC2020CA032705		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Off Label Use; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unknown		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Naprosyn			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574330	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201711-006281			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown	300 Mg		Concordia
	Arava			S	Oral	10 Mg		Not Reported
	Gold			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every Other Week		Not Reported
	Orencia			S	Subcutaneous	250 Mg		Not Reported

Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Leflunomide	S	Unknown	10 Mg, Qd	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Sodium Aurothiomalate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Unknown	20 Mg, Weekly; Solution	Not Reported
Methotrexate	S	Unknown	12.5 Mg	Not Reported
Methotrexate	S	Subcutaneous	15 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	15 Mg, Weekly	Not Reported
Salazopyrin	S	Unknown		Not Reported
Actemra	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	25 Mg	Not Reported
Enbrel	S	Unknown	50 Mg	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Every Six Weeks	Not Reported
Orencia	S	Subcutaneous	25 Mg	Not Reported
Bifidobacterium Bifidum	C			Not Reported
Prednisone	C			Not Reported
Sulfasalazine	C			Not Reported
Celebrex	C			Not Reported
Loperamide	C			Not Reported
Pantoprazole	C			Not Reported
Xeljanz	C			Not Reported
Simponi	C			Not Reported
Wellbutrin	C			Not Reported
Plaquenil	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574349	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201709-005363			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Joint Swelling; Joint Swelling; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Toxicity To Various Agents; Visual Impairment; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	400 Mg, Qd		Concordia
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	125 Mg, Weekly		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk, Solution Subcutaneous		Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported

	Depo-Medrol	C	Unk	Not Reported
	Prednisone	C	Unk	Not Reported
	Tylenol	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574376	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201805-001688			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Kevzara			S	Subcutaneous	20 Mg, Qow		Not Reported
	Leflunomide			S	Oral	20 Mg		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Cyclosporin			S	Intracardiac	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Xeljanz			C		Unk		Not Reported
	Nexium			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Vitamin D			C		Unk		Not Reported
	Magnesium			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574713	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023101		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract;	Orencia			S	Unknown			Bristol Myers Squibb

Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Actemra	S	Unknown	160 Milligram, Qwk	Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Meloxicam	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574715	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-013887			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epistaxis; Headache; Insomnia; Nausea; Osteonecrosis Of Jaw; Transaminases Increased	Risedronate			S	Oral	35 Milligram, Every Week		Aurobindo
	Plaquenil			S	Unknown	300 Milligram, Once A Day		Not Reported
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported
	Mycophenolate Mofetil			S	Oral	500 Milligram, Two Times A Day		Not Reported
	Mycophenolate Mofetil			S	Oral	1 Gram, Two Times A Day		Not Reported
	Azathioprine			C	Oral	50 Milligram, Once A Day		Not Reported
	Azathioprine			C	Oral	150 Milligram, Once A Day		Not Reported
	Azathioprine			C	Oral	100 Milligram, Two Times		Not Reported

				A Day	
	Humira	C	Subcutaneous	40 Milligram (1 Every 2 Weeks)	Not Reported
	Ketoprofen	C	Unknown	Unk	Not Reported
	Methotrexate	C	Oral	Unk	Not Reported
	Methotrexate	C	Subcutaneous	25 Milligram, Every Week	Not Reported
	Prolia	C	Subcutaneous	60 Milligram (1 Every 6 Months)	Not Reported
	Rituximab	C	Intravenous (not otherwise specified)	1 Gram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17574931	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001751			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastrointestinal Disorder	Hydroxychloroquine			S	Unknown	300-400 Unk		Concordia
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575142	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000867			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Headache; Hyperhidrosis	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Ipca
	Prednisolone			C	Unknown	Unk, Take As Directed		Not Reported
	Dermol			C	Unknown	Unk, Use As Directed		Not Reported
	Dermovate			C	Unknown	Unk, Apply 1-2 Times/Day Thinly To All Affected Areas		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575254	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023112		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, 4 Every 1 Week		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575456	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023128			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Intentional Product Use Issue; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling;	Orencia			S	Intracavernous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, 2 Every 1 Day		Not Reported

Pneumonia Viral; Soft Tissue Swelling; Synovitis	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Anakinra	C	Unknown	Not Reported
	Ativan	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	Darifenacin	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Diphenhydramine	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Kadian	C	Unknown	Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Not Reported
	Oxyneo	C	Unknown	Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Trimethoprim	C	Unknown	Not Reported
	Urispas	C	Unknown	Not Reported
	Vagifem	C	Vaginal	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575525	NON-EXPEDITED			US-PFIZER INC-2020123929		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Therapeutic Product Effect Incomplete	Sulfasalazine			S	Oral	500 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S	Oral	200 Mg, 2x/Day		Not Reported
	Xeljanz Xr			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575752	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023400		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported
	Xeljanz			C	Oral	5 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575760	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020120639			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Psoriatic Arthropathy; Swelling; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Cosentyx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17575864	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567757		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Orencia		S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate		S	Oral	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Subcutaneous	Not Reported
	Humira		S	Unknown	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Xeljanz		C	Oral	Not Reported
	Prednisone		C	Oral	Not Reported
	Lyrica		C	Unknown	Not Reported
	Arava		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17576314	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023435		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tramadol			C	Unknown	100 Milligram		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17576658	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023436			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	4 Milligram/Kilogram		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Unknown			Not Reported
	Prednisone			C	Unknown	50 Milligram, 1 Every 1 Day		Not Reported
	Prevacid			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	50 Milligram, 2 Every Q Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577389	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023448		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Carpal Tunnel Syndrome;	Orencia			S	Unknown			Bristol Myers Squibb

Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Nystatin	S	Unknown	Not Reported
	Nystatin	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Indometacin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577584	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023530			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported

	Azathioprine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577628	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023475		55 YR	Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Toxicity To Various Agents; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577694	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023552		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis Allergic; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Celebrex			C	Unknown	200 Milligram, Bid		Not Reported

	Septra	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577757	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023607		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown	100 Milligram		Not Reported
	Ativan			C	Unknown	Unk		Not Reported
	Codeine			C	Unknown	Unk		Not Reported
	Darifenacin			C	Unknown			Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Hydromorphone			C	Unknown	Unk		Not Reported
	Kadian			C	Unknown	Unk		Not Reported

Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Unk		Not Reported
Loperamide	C	Unknown	Unk		Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown			Not Reported
Omnaris	C	Unknown	Unk		Not Reported
Oxyneo	C	Unknown			Not Reported
Pantoprazole	C	Unknown			Not Reported
Restasis	C	Unknown			Not Reported
Rituximab	C	Intravenous (not otherwise specified)	Unk		Not Reported
Synthroid	C	Unknown	Unk		Not Reported
Trimethoprim	C	Unknown			Not Reported
Urispas	C	Unknown	200 Milligram		Not Reported
Vagifem	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17577988	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023859			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578006	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

BMS-2020-023868

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578076	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023929			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Prednisone	C	Unknown	30 Milligram, Qd	Not Reported
	Methotrexate	C	Oral	15 Milligram, Qwk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578415	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024447			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578458	EXPEDITED (15-DAY)		OT	US-JNJFOC-20200329683			Female	USA

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

Abdominal Pain Upper; Gastric Disorder; Gastritis; Nail Discolouration; Nail Disorder; Nausea; Pancreatitis; Skin Lesion; Tuberculosis; Vomiting; Weight Decreased	Simponi Aria	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Spironolactone	C			Not Reported
	Verapamil	C			Not Reported
	Omeprazole	C			Not Reported
	Vitamin D /00107901/	C			Not Reported
	Calcium /00060701/	C			Not Reported
	Albuterol /00139501/	C			Not Reported
	Carafate	C			Not Reported
	Dulera	C			Not Reported
	Prednisone	C		5 Mg For The First 3 Days/ / -/ / Tablets Taper Dose Down	Not Reported
	Ipratropium Bromide	C			Not Reported
	Albuterol Sulfate	C			Not Reported
	Singulair	C			Not Reported
	Claritin /00917501/	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578514	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020123955			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	20 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578942	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024664		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	400 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578947	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024594		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578950	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024375			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578991	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024991			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported

Synovitis; White Blood Cell Count Decreased	Humira		S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate		S	Oral	400 Milligram	Not Reported
	Methotrexate		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17578997	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023964		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Off Label Use; Spinal Column Injury; Surgical Failure; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown	15 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Mar-2020	17579024	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024270			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug	Orencia			S	Unknown			Bristol Myers Squibb

Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Acetaminophen	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown	20 Milligram, Qwk	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram	Not Reported
	Synthroid	C	Unknown		Not Reported
	Methotrexate	C	Unknown	Unk, Qwk	Not Reported
	Meloxicam	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	12701613	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1490		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Xeljanz	S	Oral	2 In 1 Day	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Aleve	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Prednisone Acetate	S	Unknown		Not Reported
	Naproxen	S	Unknown		Not Reported
	Leflunomide	S	Unknown	Cyclical	Not Reported
	Leflunomide	S	Unknown		Not Reported

Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Not Reported
Hcq	C	Unknown	Not Reported
Acetaminophen And Codeine	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Insulin	C	Unknown	Not Reported
Metformin	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	12911486	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-048399			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Off Label Use; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Mirtazapine			S	Unknown	15 Milligram		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	13152994	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-004666		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Surgery; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	14145032	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-095890			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Drug Ineffective; Hospitalisation; Meningitis; Off Label Use	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Actemra			S	Unknown	1 Dosage Form		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Methotrexate	S	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	14539306	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0138		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling	Kineret			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo Hydroxychloroquine			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Imuran			S				Not Reported
	Methotrexate			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S				Not Reported
	Apo-Azathioprine			S				Not Reported
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	14917725	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-071465			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	577 Milligram		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Product Effect Decreased; Treatment Failure	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	577 Absent	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	577 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	577 Absent	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	577 Milligram	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	577 Milligram	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	577 Milligram	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	577 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported

Methotrexate Sodium	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	577.0 Milligram		Not Reported
Hydroxychloroquine	S	Unknown	577 Absent		Not Reported
Desoximetasone	C	Oral	Unk		Not Reported
Cortisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	14921371	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043739		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	40 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Naproxen			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	15674968	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573976-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	15949326	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-010949			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

Leflunomide	S	Unknown		Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Xeljanz	C	Oral	5 Milligram, 2 Every 1 Day	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16073575	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05670		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported

Enbrel	S	Subcutaneous	Unknown		Not Reported
Hydroxychloroquine Sulphate	S	Unknown	Unknown		Not Reported
Desoximetasone	C	Unknown	Unknown		Not Reported
Methotrexate	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16125465	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091994			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Cyclical		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Unk Unk, Q2wk		Not Reported
	Methotrexate Sodium			S	Oral	40 Mg (Titer), Q2wk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16248273	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2761854-00		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Prednisolone			C				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16439513	EXPEDITED (15-DAY)		DS, OT	CA-SAMSUNG BIOEPIS-SB-2019-14998		8 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet	Etanercept			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Enbrel		S	Subcutaneous		Not Reported
	Leflunomide		S	Oral	Unknown	Not Reported
	Methotrexate		S	Subcutaneous		Not Reported
	Methotrexate		S	Subcutaneous	Unknown	Not Reported
	Orencia		S	Unknown	Unknown	Not Reported
	Orencia		S			Not Reported
	Plaquenil		S	Unknown	Unknown	Not Reported
	Rituximab		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Rituximab		S	Unknown	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Unknown	Not Reported
	Tocilizumab		S	Unknown	Unknown	Not Reported
	Tocilizumab		S			Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Unknown	Not Reported
	Actemra		S	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16485230	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2835174-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Head Injury; Road Traffic Accident	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16740243	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA196426		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Aclasta			S	Intravenous (not otherwise specified)	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk, Qw		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	1 Df, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported
	Tramacet			S	Unknown			Not Reported
	Actonel			C	Unknown	35 Mg, Qw		Not Reported
	Calcium			C	Unknown			Not Reported
	Lorazepam			C	Unknown	1 Mg, Qd		Not Reported
	Lyrica			C	Oral	150 Mg, Bid		Not Reported
	Metformin			C	Unknown	5 Mg, Qd		Not Reported
	Metformin			C	Unknown	500 Mg, Bid		Not Reported

Methylprednisolone Acetate	C	Subcutaneous	Unk Unk, Qmo	Not Reported
Methylprednisolone Acetate	C	Intramuscular	40 Mg, Qmo	Not Reported
Methylprednisolone Acetate	C	Subcutaneous	Unk	Not Reported
Methylprednisolone Acetate	C	Intramuscular	40 Mg, Qmo	Not Reported
Methylprednisolone Acetate	C	Unknown	Unk	Not Reported
Nortriptyline	C	Unknown	Unk	Not Reported
Nortriptyline	C			Not Reported
Premarin	C	Unknown	0.625 Mg, Unk	Not Reported
Tylenol	C	Unknown		Not Reported
Vagifem	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Nortriptyline Hydrochloride	C	Unknown	20 Mg, Qd	Not Reported
Nortriptyline Hydrochloride	C	Unknown	Unk	Not Reported
Risedronate Sodium	C	Unknown	35 Mg, Every Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	16740961	EXPEDITED (15-DAY)		HO, OT	DE-ROCHE-2386588			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Arthralgia; Arthropathy; Atrial Fibrillation; Bronchitis; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Roactemra			S	Subcutaneous			Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Ambrisentan			S	Unknown	30 Mg, Qd		Not Reported
	Ambrisentan			S	Unknown	30 Milligram, Qd		Not Reported
	Lyrica			S	Unknown	100 Mg, Tid (1 - 1 - 1)		Not Reported
	Sildenafil Citrate			S	Unknown	60 Milligram, Daily Dose		Not Reported
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1)		Not Reported
	Spasmolyt			S	Unknown	30 Mg (0 -0 -1)		Not Reported
	Spasmolyt			S	Unknown	15 (Unit Not Specified), Qd		Not Reported

					((1 - 0 - 0)	
	Omeprazole		S	Oral	1 Df, Bid (1 - 0 - 1)	Not Reported
	Ramipril		S	Oral	1 Df, Bid (1 - 0 - 1)	Not Reported
	Eliquis		S	Unknown	2.5 Mg Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17390605	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-006953		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Milligram		Not Reported
	Xeljanz			S	Oral	5 Milligram(2 Every One Week)		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17399035	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010345		57 YR	Male	CAN

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

Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Orencia	S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra	S	Unknown			Not Reported
	Anakinra	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Arava	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Gold	S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Methotrexate	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate	S	Unknown			Not Reported
	Sulfasalazine	S	Unknown	500 Milligram		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Apo-Leflunomide	S	Unknown			Not Reported
	Ilaris	C	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown			Not Reported
	Rituximab	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578578	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023106		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Drug Ineffective;	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb

Drug Intolerance; Mouth Ulceration; Vasculitic Rash	Orencia	S	Unknown	500 Unk	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
	Anakinra	S	Subcutaneous	100 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Q2wk	Not Reported
	Leflunomide	S	Oral	20 Unk	Not Reported
	Methotrexate	S	Unknown	Unk, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Qd	Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578721	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001831			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cushingoid; Diarrhoea; Nausea; Nightmare; Renal Pain; Sleep Terror; Therapeutic Response Decreased; Treatment Failure; Weight Increased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Methotrexate			S	Oral	25 Mg, Weekly		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Weekly		Not Reported
	Azathioprine			C				Not Reported
	Humira			C		Unk		Not Reported
	Leucovorin			C		Unk		Not Reported
	Prevnar 13			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578725	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201703-001913			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Arthropathy; Condition Aggravated; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Finger Deformity; Limb Operation; Off Label Use; Pain; Peripheral Swelling; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Urticaria; Wrist Surgery	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unknown, Tablet		Concordia
	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Apo-Hydroxyquine			S	Unknown	Unknown		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unknown		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rocuronium Bromide			S	Unknown	Unknown		Not Reported
	Rocuronium Bromide			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unknown		Not Reported
	Benzylpenicillin Sodium			S	Unknown	Unknown		Not Reported
	Phenoxymethylpenicillin Potassium			S	Unknown	Unk		Not Reported

Rituximab	S	Unknown	Unk		Not Reported
Prednisone	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578782	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023426		72 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	640 Milligram, Q4wk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578902	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568831		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Tacrolimus	S	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17578910	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown	162 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579095	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001832			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Diarrhoea; Diarrhoea; Nausea; Renal Failure	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Leflunom|De			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579314	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES			Unknown	USA

LIMITED-IPC-2020-US-000918

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Cardiac Failure; Cardiomyopathy; Cardiotoxicity; Renal Impairment	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
	Furosemide			S	Intravenous (not otherwise specified)	Unk		Ipca
	Prednisone			C	Unknown	Unk		Not Reported
	Mycophenolate			C	Unknown	Unk		Not Reported
	Rituximab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579324	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1483			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Other			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579472	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567801		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Rituxan			S	Intravenous drip			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579865	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1208924		45 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Levofloxacine			S	Oral	1000 Mg		Teva
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	2 Dosage Forms		Not Reported

	Ideos	S	Oral	2 Dosage Forms	Not Reported
	Acarizax	S	Oral		Not Reported
	Lutenyl	C			Not Reported
	Cortancyl	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17579885	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025463		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17580009	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020124022			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Methotrexate Sodium			S		20 Mg, Weekly (Therapy Duration: 7 Years)		Pfizer
	Enbrel			S		Unk (Therapy Duration: 9 Months)		Pfizer
	Rituximab			S		Unk (Therapy Duration: 3 Years)		Not Reported

	Humira	S	Subcutaneous	40 Mg, Unk (1 Every 2 Weeks, Therapy Duration: 346 Days)	Not Reported
	Hydroxychloroquine	S		200 Mg, 2x/Day (Therapy Duration: 9 Years)	Not Reported
	Remicade	S		Unk (Therapy Duration: 2 Years)	Not Reported
	Xeljanz	C		5 Mg, 2x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17580222	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1336			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Off Label Use	Anakinra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17580309	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023667		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone Acetate	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17580690	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023759		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; Drug Ineffective; Fall; Fatigue; Femur Fracture; Intentional Product Use Issue; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Unknown	12.5 Milligram		Not Reported
	Folic Acid			C	Unknown			Not Reported

	Hydroxychloroquine Sulfate			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581498	NON-EXPEDITED			US-PFIZER INC-2020122192		72 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581796	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025438			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	12.5 Milligram, Bid		Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581877	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Abnormal Weight Gain; Alopecia; Chest Pain; Dizziness; Dyspnoea; Fatigue; Joint Swelling; Nausea; Photosensitivity Reaction; Syncope; Tremor	Hydroxychloroquine 200 Mg			S	Oral	Quantity:2 Tablet(S);	5 YR	Not Reported
	Prem-Pro 0.3mg/1.5mg			C				Not Reported
	Ventolin Inhaler			C				Not Reported
	Vit B (Complex)			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin D			C				Not Reported
	Zinc			C				Not Reported
	Calcium			C				Not Reported
	Magnesium			C				Not Reported
	Cod Liver Oil			C				Not Reported
	Grape Seed Extract			C				Not Reported
	St Johns Wort			C				Not Reported
	Stainging Nettle			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581909	EXPEDITED (15-DAY)		DE, HO, LT, OT	NVSC2020CA083709			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S	Unknown	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

Apo-Leflunomide	S				Not Reported
Enbrel	S	Unknown	Unk		Not Reported
Enbrel	S				Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S				Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S				Not Reported
Sulfasalazine	S	Unknown	500 Mg		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581930	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1030615		44 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Marrow Failure; Drug Interaction	Methotrexate			S	Subcutaneous	10 Milligram, Qw		Not Reported
	Dolquine			S	Oral	200 Milligram, Bid (12 Hours)		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581934	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA083373			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug	Ilaris			S	Intravenous (not otherwise specified)	Unk		Novartis

Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris	S	Subcutaneous	Unk	Novartis
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S			Not Reported
	Methotrexate Sodium	S	Intra-arterial	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S			Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Oxyquinoline Sulfate	S	Unknown	Unk	Not Reported
	Oxyquinoline Sulfate	S			Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581956	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA083719		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Ilaris			S	Unknown	Unk		Novartis
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Novartis
	Ilaris			S	Subcutaneous	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S				Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported

Remicade	S	Unknown	Unk		Not Reported
Remicade	S				Not Reported
Remicade	S	Unknown	Unk		Not Reported
Remicade	S				Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Sodium Aurothiomalate	S				Not Reported
Sulfasalazine	S	Unknown	500 Mg		Not Reported
Sulfasalazine	S				Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17581969	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1030618		30 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agranulocytosis	Mycophenolate Mofetil			S	Oral	500 Milligram, Bid		Not Reported
	Dolquine			S	Oral	200 Milligram, Bid		Mylan
	Rituximab			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17583060	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025465		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous drip	Not Reported
	Humira	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17583075	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025482			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anal Fissure; Bronchitis; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Orencia			S	Endocervical			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17583096	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025534			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported

	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2020	17583157	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025394			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	12889782	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013285		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral	5 Mg, Q.12h		Apotex
	Apo-Leflunomide			S	Unknown	Unk Unk, Bid		Apotex
	Apo-Naproxen			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Q.12h		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

Abnormal; Synovitis	Adalimumab		S	Subcutaneous		Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Actemra		C	Unknown	Unk	Not Reported
	Methotrexate		C	Unknown	Unk	Not Reported
	Humira		C	Subcutaneous	Unk	Not Reported
	Orencia		C	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil /00072602/		C	Unknown		Not Reported
	Folic Acid		C	Unknown		Not Reported
	Hydroxychloroquine Sulfate		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	12914312	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091576		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Urticaria	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Sodium Aurothiomalate			S	Unknown	Unk, Qwk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk, Qd		Not Reported
	Gold			S	Unknown	Unk, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	22.5 Milligram, Qwk		Not Reported
	Methotrexate Sodium			S	Parenteral	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	22.5 Milligram, Qwk	Not Reported
Methotrexate	S	Parenteral	25 Milligram, Qwk	Not Reported
Infliximab	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Phosphate	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Subcutaneous	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Tocilizumab	C	Unknown	Unk	Not Reported
Azathioprine	C	Unknown	Unk, Qd	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Minocycline	C	Unknown	Unk	Not Reported
Penicillamine	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	6 Milligram, Bid	Not Reported
Actemra	C	Unknown	Unk	Not Reported
Cyclosporine	C	Unknown	Unk	Not Reported
Prednisolone	C	Unknown	6 Milligram, Qd	Not Reported
D-Penicillamine	C	Unknown	Unk	Not Reported
Phenylbutazone	C	Unknown		Not Reported
Methotrexate	C	Parenteral	25 Milligram, Q4wk	Not Reported

	Humira	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13057420	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1869749		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13057569	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015705		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling;	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex

Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Qd	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Advil /00109201/	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Ketorolac	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	20 Mg, Q.Wk.	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13059083	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015740		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Joint Swelling; Pain; Shoulder Operation; Therapeutic Response Decreased	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13180365	EXPEDITED (15-DAY)		HO, OT	PHHY2017CA012856		60 YR	Female	CAN

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

Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Methotrexate		S	Unknown	Unk	Not Reported
	Neoral		S	Unknown	Unk Unk, Unknown	Novartis
	Celebrex		S	Unknown	Unk Unk, Unknown	Not Reported
	Cimzia		S	Subcutaneous	Unk Unk, Unknown	Not Reported
	Enbrel		S	Unknown	Unk Unk, Unknown	Not Reported
	Humira		S	Subcutaneous	Unk Unk, Unknown	Not Reported
	Imuran		S	Unknown	Unk Unk, Unknown	Not Reported
	Plaquenil		S	Unknown	Unk Unk, Unknown	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk Unk, Unknown	Not Reported
	Azathioprine		S	Unknown	Unk	Not Reported
	Celecoxib		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	13968018	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017267		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme Increased; Hypokinesia; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Intravenous (not	500 Mg, Unk		Not Reported

Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Delayed			otherwise specified)			
	Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Unk		Not Reported
	Cortisone	C	Unknown			Not Reported
	Prednisone	C	Unknown	5 Mg, Qd		Not Reported
	Tylenol Arthritis	C	Unknown			Not Reported
	Naprosyn /00256201/	C	Unknown			Not Reported
	Rabeprazole	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	14692979	EXPEDITED (15-DAY)		DE, HO, LT, OT	PHHY2018CA055436		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Novartis
	Ilaris			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S				Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported

Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Sulfasalazin	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazin	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Marijuana	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Minocycline	S	Unknown		Not Reported
	Oxyquinoline Sulfate	S	Unknown		Not Reported
	Oxyquinoline Sulfate	S			Not Reported
	Cannabis Sativa	S	Unknown		Not Reported
	Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
	Xeljanz	C	Oral	2 Df, Qd	Not Reported

	Xeljanz	C	Unknown	5 Mg		Not Reported
	Rituximab	C	Unknown			Not Reported
	Kineret	C	Unknown	Unk		Not Reported
	Lyrica	C	Unknown			Not Reported
	Prednisone	C	Unknown	1 Df, Qd		Not Reported
	Urelumab	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15042955	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021658		54 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Etanercept			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Q.Wk.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Leflunomide			C	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15386769	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-20713376		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder; Weight Increased	Warfarin Sodium			S	Unknown	Unk		Bristol Myers Squibb
	Metformin Hydrochloride			S	Unknown	Unk		Bristol Myers Squibb
	Metformin Hydrochloride			S	Unknown			Bristol Myers Squibb
	Cymbalta			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Xarelto			C	Unknown	Unk		Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15411090	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186044		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Methotrexate		S	Subcutaneous	Not Reported
	Orencia		S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Not Reported
	Sodium Aurothiomalate		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15635401	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105895			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	200.0 Mg, Qd		Not Reported
	Methotrexate			S	Oral	25.0 Mg, Qwk		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Gold Sodium Thiomalate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15680306	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2575130-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Apo-Hydroxyquine	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rocuronium	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15843598	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190118854		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Positive	Actemra	S	Unknown	Not Reported
	Arava	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Arthrotec	C	Oral	Not Reported
	Gold	C	Unknown	Not Reported
	Imuran	C	Unknown	Not Reported
	Vitamin D	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15867265	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190123564		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Simponi Iv			S	Intravenous (not otherwise specified)			Not Reported
	Simponi Iv			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	15946323	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-010990		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			C	Unknown			Not Reported
	Codein			C	Unknown			Not Reported
	Lyrica			C	Oral	Unk		Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16125329	EXPEDITED (15-DAY)		OT	PHHY2019CA064258		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Ciclosporin			S	Subcutaneous			Novartis
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg,Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Every 1 Week		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Every 1 Week		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg, Unk		Not Reported
	Rituxan			S	Intravenous drip	Unk		Not Reported
	Rituxan			S	Intravenous drip	Unk		Not Reported

	Sulfasalazine	S	Oral	Unk		Not Reported
	Xeljanz	C	Unknown	Unk, Qd		Not Reported
	Xeljanz	C	Oral	10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16128012	EXPEDITED (15-DAY)		OT	PHHY2019CA064350		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Ciclosporin			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituxan	S	Oral	Unk		Not Reported
	Sulfasalazine	S	Oral	Unk		Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16480411	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-16027		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16536778	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1071381			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Ciprofloxacin			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Clindamycin			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Enalapril			S	Unknown			Teva
	Hctz			S	Unknown			Ivax
	Losartan			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Metoprolol Tartrate			S	Unknown			Not Reported
	Moxifloxacin Hydrochloride			S	Unknown			Teva
	Moxifloxacin Hydrochloride			S	Unknown			Teva
	Pantoprazole Magnesium			S	Unknown			Teva
	Penicillin G			S	Unknown			Teva
	Cefalexin			S	Unknown			Not Reported
	Enalapril Maleate			S	Unknown			Teva
	Losartan			S	Unknown			Teva
	Arava			S	Unknown			Not Reported
	Biaxin			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydralazine Hydrochloride			S	Unknown			Not Reported
	Keflex			S	Unknown			Not Reported
	Levaquin			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Pariet	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Diazide (Gliclazide)	S	Unknown		Not Reported
Lopressor	S	Unknown		Not Reported
Tecta	S	Unknown		Not Reported
Xeljanz	S	Oral	100 Milligram Daily;	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Isoniazid	S	Unknown		Not Reported
Cipro	S	Unknown		Not Reported
Penicillin Nos	S	Unknown		Not Reported
Esomeprazole	C	Unknown		Not Reported
Gold	C			Not Reported
Hydroxychloroquine	C			Not Reported
Iron Sucrose	C	Unknown		Not Reported
Prednisone	C	Unknown	8.5 Milligram Daily;	Not Reported
Colchicine	C			Not Reported
Coversyl [Perindoprilerbumine]	C			Not Reported
Hydroxychloroquine Sulfate	C	Unknown		Not Reported
Leucovorin [Folinic Acid]	C			Not Reported
Levothyroxine Sodium	C			Not Reported
Ranitidine	C			Not Reported
Venofer	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16767573	EXPEDITED (15-DAY)		OT	PHHY2018CA068442		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Ciclosporin			S	Unknown			Novartis
	Adalimumab			S	Subcutaneous	40 Mg, Biw		Not Reported

Rituximab	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Oral	20 Mg	Not Reported
Methotrexate Sodium	S	Subcutaneous	20 Mg	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Biw	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Apo Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo Hydroxyquine	S	Oral	Unk	Not Reported
Apo Leflunomida	S	Unknown		Not Reported
Enbrel	S	Unknown	50 Mg, Biw	Not Reported
Enbrel	S	Unknown	50 Mg, Biw	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Methotrexate	S	Oral	20 Mg, Qw	Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Qw	Not Reported
Methotrexate	S	Oral	20 Mg, Qw	Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Qw	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Orencia	S	Unknown	75 Mg, Qw	Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown	40 Mg, Biw	Not Reported

	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
	Risedronate	C	Oral	35 Mg, Qw	Not Reported
	Rituxan	C	Intravenous (not otherwise specified)		Not Reported
	Arava	C	Oral	1 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16792405	EXPEDITED (15-DAY)		HO	JP-GLAXOSMITHKLINE-JP2019JPN160709		50 YR	Male	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Focal Segmental Glomerulosclerosis	Benlysta			S	Subcutaneous	200 Mg		Glaxosmithkline
	Benlysta			S	Subcutaneous	200 Mg		Glaxosmithkline
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Predonine			C		Unk		Not Reported
	Mycophenolate Mofetil Capsule			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16982578	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-20191009548		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased;	Otezla			S	Unknown	60 Milligram		Celgene
	Otezla			S	Unknown			Celgene
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	500 Milligram		Not Reported

Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Cimzia	S	Subcutaneous		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Ibuprofen	S	Oral		Not Reported
	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
	Infliximab	S	Oral		Not Reported
	Infliximab	S			Not Reported
	Methotrexate	S	Unknown	1.7143 Milligram	Not Reported
	Methotrexate	S	Unknown	1.7857 Milligram	Not Reported
	Methotrexate	S	Unknown	1.4286 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	2.5 Milligram	Not Reported
	Methotrexate	S	Unknown	1.4286 Milligram	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	7.1429 Milligram	Not Reported
	Methotrexate	S	Unknown	5.7143 Milligram	Not Reported
	Methotrexate	S	Unknown	6.8571 Milligram	Not Reported
	Methotrexate	S	Unknown	17.5 Milligram	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown	1000 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Subcutaneous		Not Reported
Sulfasalazine	S	Endocervical		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Diphenhydramine Hydrochloride	C	Unknown		Not Reported
Colchicine	C	Oral		Not Reported
Dexilant	C	Unknown		Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Gravol	C	Unknown		Not Reported
Mogadon	C	Oral		Not Reported
Nitrazepam	C	Oral	5 Milligram	Not Reported
Oxycodone	C	Unknown		Not Reported
Prednisone	C	Unknown	20 Milligram	Not Reported
Uloric	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	16988122	EXPEDITED (15-DAY)		OT	CA-SA-2019SA298961			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Abnormal	Cefixime			S	Unknown	Unk		Not Reported
	Bisoprolol Salt Not Specified			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Morphine Salt Not Specified			S				Not Reported
	Nifedipine			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Sanofi
	Prednisone			S	Unknown			Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported
	Zantac			S	Unknown			Sanofi
	Zopiclone			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Oral	100 Mg		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Mg/Kg Q0, 2, 6, 8 Weeks		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17281615	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518250		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Naproxen	S	Unknown		Not Reported
	Kineret	S	Subcutaneous	Solution Subcutaneous, 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes	Not Reported
	Acetaminophen	C			Not Reported
	Diphenhydramine Hydrochloride	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C			Not Reported
	Lasix [Furosemide]	C			Not Reported
	Methylprednisolone	C			Not Reported
	Naprosyn E	C			Not Reported
	Oxycontin	C	Unknown	Tablet (Extended Release)	Not Reported
	Oxyneo	C	Unknown	Tablet (Extended Release)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17455140	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Maternal Exposure During Pregnancy; Toxicity To Various Agents	Hydroxychloroquine			S		Unk		Concordia
	Hydroxychloroquine			S		400 Mg, Qd		Concordia
	Hydroxychloroquine			S		Unk		Concordia
	Azathioprine			S		50 Mg, Qd		Not Reported
	Azathioprine			S		Retreatment With Low-Dose 50 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Prednisone			S		Unk		Not Reported
	Prednisone			S		Moderate Doses Of Prednisone		Not Reported
	Prednisone			S		2.5 Mg, Qd		Not Reported
	Belimumab			S		Unk		Not Reported
	Belimumab			S		10 Mg/Kg, Monthly		Not Reported
	Belimumab			S		Unk, Resumed 2 Weeks After Delivery		Not Reported
	Mycophenolate			C		Unk		Not Reported
	Mycophenolate			C		Switching Back		Not Reported
	Mycophenolate			C		Continued During The Initial 6 Months Of Belimumab Infusions And Then Tapered Off		Not Reported
	Warfarin			C		Unk		Not Reported
	Warfarin			C		Resumed Warfarin		Not Reported
	Low-Molecular-Weight Heparin			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17533248	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200309558		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Off Label Use; Product Use In Unapproved Indication; Psoriatic Arthropathy; Rheumatoid Arthritis; Sleep Disorder; Uveitis	Stelara			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Minocycline	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583205	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024031		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	500 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Q12h		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583207	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025557		56 YR	Female	CAN

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

Drug Ineffective; Pulmonary Fibrosis	Orencia		S	Unknown	Unk	Bristol Myers Squibb
	Hydroxychloroquine Sulfate		S	Unknown	400 Milligram, Qd	Not Reported
	Rituximab		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583283	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000888			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Warfarin Sodium			S	Unknown	Unk		Ipca
	Clopidogrel			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	Unk		Not Reported
	Apixaban			S	Unknown	Unk		Not Reported
	Rivaroxaban			S	Unknown	Unk		Not Reported
	Low Molecular Weight Heparin			C	Unknown	Unk		Not Reported
	Isoniazid			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583434	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571059			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Off Label Use	Rituxan			S	Subcutaneous			Not Reported
	Anakinra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583491	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568766			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported
	Desoximetasone			C	Subcutaneous			Not Reported
	Diclofenac			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583496	EXPEDITED (15-DAY)		OT	CA-ROCHE-2569483		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Single Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583521	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023661		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Drug	Orencia			S	Intravenous (not	Unk		Bristol Myers Squibb

Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure			otherwise specified)		
	Actemra	S	Unknown	Unk	Not Reported
	Alendronate Sodium	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Milligram	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	40 Milligram	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Q12h	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Diclofenac	C	Unknown	50 Milligram	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583547	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571158			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Increased; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583562	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1479		59 YR	Male	CAN

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

Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)		S	Unknown	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583564	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1490			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583582	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1504			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Psoriatic Arthropathy; Swelling; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583834	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001844			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Neutropenia; Rash	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	10 Mg, Qd		Not Reported

Arava	S	Unknown	20 Mg, Qd		Not Reported
Salazopyrin	C		Unk		Not Reported
Solganal	C		Unk		Not Reported
Methotrexate	C		Unk		Not Reported
Codeine	C		Unk		Not Reported
Flurbiprofen	C		Unk		Not Reported
Cortisone	C	Intra-articular	Unk		Not Reported
Tylenol	C		Unk		Not Reported
Folic Acid	C		Unk		Not Reported
Gold	C		Unk		Not Reported
Prevacid	C		Unk		Not Reported
Penicillamine	C		Unk		Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583875	EXPEDITED (15-DAY)		OT	CA-ROCHE-2523564		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Diastolic Abnormal; Bone Marrow Toxicity; C-Reactive Protein Increased; Intentional Product Use Issue; Neuropathy Peripheral; Off Label Use; Paraesthesia; Rash; Thrombocytopenia	Rituxan			S	Intravenous (not otherwise specified)	1 Every Week For 4 Dose		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Lyrica			C				Not Reported
	Synthroid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583878	NON-EXPEDITED		DE	NVSC2020US084343		30 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Melanoma Stage Iv; Malignant Neoplasm Progression	Dabrafenib			S	Unknown	150 Mg, Bid		Novartis
	Dabrafenib			S				Novartis
	Trametinib			S	Unknown	2 Mg, Qd		Not Reported
	Trametinib			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk, 400 To 600 Mg, Bid		Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583912	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567774		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17583952	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568809			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Rituximab			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584003	EXPEDITED (15-DAY)		HO	CA-ROCHE-2571253			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584031	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-241562		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Drug Resistance; Gastrointestinal Disorder; Pseudomonal Skin Infection; Therapeutic Product Effect Incomplete; Treatment Failure	Triamcinolone			S		Unk		Ranbaxy
	Tacrolimus			S	Topical	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Sun
	Clobetasol			S	Topical	Unk		Taro
	Pentoxifylline			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584210	EXPEDITED (15-DAY)		OT	NVSC2020CA083918		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Remicade			S	Unknown	3 Mg (Powder For Solution)		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584216	EXPEDITED (15-DAY)		OT	NVSC2020CA082940		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Adalimumab			S	Subcutaneous	40 Mg, Unknown		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unknown		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unknown		Not Reported
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Xeljanz			S	Oral	Unk		Not Reported
	Xeljanz			S	Oral	2 Df, Qd		Not Reported
	Sulfasalazine			S	Oral	1 Df, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unknown		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Plaquenil			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	75 Mg, Qmo		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unknown		Not Reported

Hydroxychloroquine	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine	S	Oral	Unk		Not Reported
Hydroxychloroquine	S	Oral	2000 Mg, Bid		Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S	Unknown	40 Mg, Q2w		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unknown		Not Reported
Arava	C	Oral	1 Df, Qd		Not Reported
Cimzia	C	Subcutaneous	1 Df, Q2w		Not Reported
Risedronate	C	Oral	1 Df, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584497	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020125866			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Speech Disorder Developmental; Treatment Failure	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584625	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020127462		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584658	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020127350			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Infection; Leukopenia; Neutropenia; Therapeutic Response Decreased	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17584988	EXPEDITED (15-DAY)		OT	GB-TORRENT-00023236		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Apixaban			S	Unknown	Unknown		Unknown
	Warfarin			S	Unknown	Unknown		Unknown
	Rivaroxaban			S	Unknown	Unknown		Unknown
	Clopidogrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Unknown
	Atorvastatin			S	Unknown	Unknown		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585091	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568730			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	Solution		Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Amoxicillin Trihydrate;Clavulanate Potassium			C	Unknown			Not Reported
	Amoxil [Amoxicillin]			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585193	EXPEDITED (15-DAY)		OT	CA-ROCHE-2570007			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Eczema; Sepsis; Urinary Tract Infection	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported

Cbd Oil	C		Not Reported
Dronabinol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585240	EXPEDITED (15-DAY)		OT	NVSC2020CA083916		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Methotrexate			S	Subcutaneous	20 Mg, Unknown		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Neoral			S	Oral	Unk		Novartis
	Rituximab			S	Endocervical	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Novartis
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unknown		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unknown		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution)		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Xeljanz			C	Unknown	5 Mg, Qd 2 Every 1 Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585302	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075362		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Oral			Sanofi
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous	Unk, 1x		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiosulfate			C				Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Qw		Not Reported
	Prednisone			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585303	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075074		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Drug Intolerance; Joint Swelling; Rheumatoid Factor Positive; X-Ray Abnormal	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Tofacitinib Citrate			S				Not Reported
	Actemra			S				Not Reported
	Diovan			C				Not Reported
	Docosahexanoic Acid;Eicosapentaenoic Acid			C				Not Reported
	Sertraline			C				Not Reported
	Valtrex			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585304	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075084		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Arava			S	Unknown			Sanofi
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585306	EXPEDITED (15-DAY)		OT	CA-SA-2020SA074997			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colitis Microscopic; Gastrointestinal Disorder; Rash	Plaquenil			S		Unk G		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			C	Subcutaneous	25 Mg, Qw		Not Reported
	Sulfasalazine			C		2 G		Not Reported
	Venlafaxine Hydrochloride			C		Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585763	EXPEDITED (15-DAY)		OT	NVSC2020CA083797		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis

Neoral	S	Subcutaneous	Unk		Novartis
Cyclosporine	S	Unknown	Unk		Novartis
Methotrexate	S	Oral	20 Mg		Not Reported
Methotrexate	S	Subcutaneous	Unk		Not Reported
Apo-Leflunomide	S	Unknown	Unk		Not Reported
Actemra	S	Intravenous drip	8 Mg/Kg, Unk		Not Reported
Actemra	S	Intravenous drip	8 Mg/Kg, Unk		Not Reported
Enbrel	S	Subcutaneous	500 Mg (Every 1 Weeks)		Not Reported
Orencia	S	Subcutaneous	125 Mg		Not Reported
Plaquenil	S	Oral	Unk		Not Reported
Plaquenil	S	Subcutaneous	Unk		Not Reported
Remicade	S	Intravenous drip	3 Mg/Kg,Unk		Not Reported
Xeljanz	C	Oral	5 Mg (2 Every 1 Day)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585786	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1031634		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Transient Ischaemic Attack; Treatment Failure	Atorvastatin			S	Unknown	Unk		Not Reported
	Clopidogrel			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585836	EXPEDITED (15-DAY)		OT	NVSC2020CA083902			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	20 Mg, (16 Years)		Not Reported
	Neoral			S	Oral	20 Mg (16 Years)		Novartis
	Enbrel			S	Subcutaneous	50 Mg (3 Months)		Not Reported

	Plaquenil	S	Oral	20 Mg (16 Years)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3.0 Mg/Kg (12 Years)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17585895	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025893		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Drug Ineffective; Fall	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17586685	NON-EXPEDITED		DE	NVSC2020US084340		59 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Melanoma Stage Iv; Malignant Neoplasm Progression	Dabrafenib			S	Oral	150 Mg, Bid		Novartis
	Dabrafenib			S				Novartis
	Trametinib			S	Oral	2 Mg, Qd		Not Reported
	Trametinib			S				Not Reported
	Hydroxychloroquine			S	Oral	400- 600 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	600 Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17586718	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-		67 YR	Female	CAN

2015347561

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dyspnoea; Lower Respiratory Tract Infection; Pain	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Arava			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17586974	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025902			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Orencia			S	Endocervical			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587086	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024299		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated	Orencia			S	Intravenous (not	Unk		Bristol Myers Squibb

Peptide Antibody Positive; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis			otherwise specified)		
	Actemra	S	Subcutaneous	Unk	Not Reported
	Anakinra	S	Subcutaneous	100 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	300 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Risedronate	S	Oral	35 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587200	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2018488256		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileus; Intestinal	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

Obstruction; Musculoskeletal Stiffness; Off Label Use; Product Use In Unapproved Indication; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine		S	Unknown	Unk	Not Reported
	Orencia		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo Hydroxyquine		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown	Unk	Not Reported
	Prednisone		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587396	EXPEDITED (15-DAY)		OT	NVSC2020CA066714		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Cyclosporine			S	Subcutaneous	Unk		Novartis
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not	3 Mg/Kg		Not Reported

			otherwise specified)		
	Humira	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz Xr	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587547	EXPEDITED (15-DAY)		OT	NVSC2020CA084494		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Neoral			S	Subcutaneous			Novartis
	Neoral			S	Unknown	Unk		Novartis
	Cyclosporine			S	Unknown			Novartis
	Leflunomide			S	Unknown	20.0 Mg, Qd		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate Sodium			S	Subcutaneous	20.0 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qw		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3.0 Mg		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported

	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Cimzia	C	Subcutaneous	200.0 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587578	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1031637		50 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Disease Progression; Pseudomonas Infection; Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	60 Milligram		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Mylan
	Dapsone			S	Unknown	Unk		Mylan
	Rituximab			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17587783	NON-EXPEDITED			NVSC2020US083346			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Xolair			S	Unknown	Unk, Q4w		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxyzine			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown			Not Reported
	Dupilumab			S	Unknown	Unk		Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Lycor			S	Unknown			Not Reported
	Singulair			S	Unknown			Not Reported

	Plaquenil		S	Unknown		Not Reported
	Prednisone		C	Unknown	1 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588061	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020126107			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown			Pfizer
	Enbrel			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Codeine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588436	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025383		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Milligram		Bristol Myers Squibb
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituximab			S	Intravenous drip	2000 Milligram		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Xeljanz	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588455	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588457	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025454			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17588491	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026044		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported
	Asacol			S	Unknown	800 Mg 3 Every 2 Days		Not Reported
	Diamicron			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gliclazide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram		Not Reported
	Atacand Plus			C	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			C	Unknown	Unk		Not Reported
	Diphenhydramine			C	Oral	50 Milligram		Not Reported

Ebastine	C	Unknown	Unk		Not Reported
Ferrous Gluconate	C	Unknown			Not Reported
Folic Acid	C	Unknown			Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
Methylprednisolone Acetate	C	Intra-articular	Unk		Not Reported
Rosuvastatin Calcium	C	Unknown	Unk		Not Reported
Tylenol	C	Unknown	Unk		Not Reported
Vitamin D3	C	Unknown	Unk		Not Reported
Acetaminophen	C	Oral	650 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2020	17591609	DIRECT	Y	LT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Haemodialysis; Intensive Care	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	11480152	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20150902732			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Back Pain; C-Reactive Protein Abnormal; Cataract; Cerebrovascular Accident; Crying; Deformity; Depression; Disability; Drug Ineffective; Dry Eye; Dyspnoea; Fatigue; Fine Motor Skill Dysfunction; Foot Deformity; Gait	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Senokot			C	Unknown			Not Reported
	Coversyl			C	Unknown			Not Reported
	Percocet			C	Unknown			Not Reported

Disturbance; Hand Deformity; Hepatic Enzyme Increased; Hepatitis C; Hypokinesia; Impaired Healing; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Muscle Atrophy; Muscle Spasms; Musculoskeletal Disorder; Musculoskeletal Pain; Myalgia; Papule; Peripheral Swelling; Procedural Pain; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Arthritis; Rheumatoid Nodule; Shoulder Deformity; Surgical Failure; Swelling; Weight Decreased; Wrist Deformity	Ativan	C	Sublingual	Night At Bedtime	Not Reported
	Lovastatin	C	Unknown		Not Reported
	Flexeril	C	Oral		Not Reported
	Flexeril	C	Oral		Not Reported
	Cyclobenzaprine Hydrochloride	C	Subcutaneous		Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	12367074	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-034237		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Unknown	760 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Alendronate Sodium			S	Oral	70 Milligram, Qwk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Enbrel	S	Unknown	25 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Q2wk	Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Unknown	25.0 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	70 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	360 Milligram, Qmo	Not Reported
	Simponi	S	Unknown	680 Milligram, Qmo	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Q4wk	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported

Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	12 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Q4wk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
Rituximab	S	Unknown	1000 Milligram, Qd	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	360 Milligram, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	680 Milligram, Q4wk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	2.68 Milligram, Q4wk	Not Reported
Myochrysine	S	Parenteral	50 Milligram, Qmo	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Q2wk	Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	500 Milligram	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram, Qmo	Not Reported
Tocilizumab	S	Unknown	680 Milligram, Q4wk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported

Alendronic Acid	S	Unknown	70 Milligram, Qwk		Not Reported
Etanercept	S	Unknown	25.0 Milligram, Qwk		Not Reported
Etanercept	S	Unknown	50 Milligram, Qwk		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Naproxen	S	Unknown			Not Reported
Azathioprine	S	Unknown			Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Qcycle		Not Reported
Celebrex	S	Unknown			Not Reported
Prednisone	C	Unknown	10 Milligram, Qd		Not Reported
Prednisone	C	Unknown	20 Milligram		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Ciclosporin	C	Unknown	150 Milligram 1 Every 24 Days		Not Reported
Ciclosporin	C	Unknown	150 Milligram, Qd		Not Reported
Prednisolone	C	Unknown	10 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	12883751	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013303		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis;	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Apo-Prednisone			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Unk, Unk		Not Reported

Stress Fracture; Vomiting; Wrist Deformity	Orencia		S	Unknown		Not Reported
	Remicade		S	Intravenous (not otherwise specified)		Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Xeljanz		S	Oral	5 Mg, Unk	Not Reported
	Plaquenil /00072602/		S	Unknown		Not Reported
	Plaquenil /00072602/		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	12893895	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20150810477		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Nasopharyngitis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

	Acetaminophen	C	Not Reported
	Arava	C	Not Reported
	Codeine	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	13058845	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015768		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk, Q.Wk.		Not Reported
	Gold			S	Unknown	Unk, Qd		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Parenteral	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Ciclosporin			C	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	Unk Unk, Qd		Not Reported

Penicillamine	C	Unknown	Unk		Not Reported
Minocycline	C	Unknown	Unk		Not Reported
Prednisolone	C	Unknown	6 Mg, Qd		Not Reported
Tocilizumab	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	6 Mg, Bid		Not Reported
Actemra	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	13059040	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015749		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Condition Aggravated; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Sulfasalazin			S	Unknown	2 G, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	300 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	13059056	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015753		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Leflunomide			S		20 Mg, Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	2 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Mg, Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	2.5 Mg, Unk		Not Reported
	Orencia			S	Subcutaneous	250 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	13244457	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006744			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia;	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20.0 Mg, Qd		Apotex

Rash; Visual Impairment	Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Qd	Not Reported
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	13251590	EXPEDITED (15-DAY)		CA, OT	CA-APOTEX-2017AP006777		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Apo-Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	22.5 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S				Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Prednisone			C	Oral	5 Mg, Qd		Not Reported

	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	13519394	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038533		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Underdose	Orencia			S	Subcutaneous	150 Mg, Qmo		Bristol Myers Squibb
	Sulfasalasin			S	Unknown	500 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Celebrex			S	Unknown	200 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naprosyn [Naproxen]			S	Unknown	500 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	14628698	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-037929		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	1 Df, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Methotrexate Sodium	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Q2wk	Not Reported
Xeljanz	S	Oral	5 Milligram, Every One Day	Not Reported
Xeljanz	S	Oral	5 Milligram, Q2wk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Lyrica	S	Oral	Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Prednisone	C	Oral	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Lyrica	C	Unknown		Not Reported
Xeljanz	C	Oral	5 Milligram, Q2wk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	14633459	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019566		51 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Drug Ineffective; Enterocolitis; Off Label Use;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported

Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Methotrexate	S	Unknown	25 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	15049818	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015756		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Leflunomide			S	Oral			Apotex
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	15076377	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016010			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

Plaquenil /00072602/	S	Unknown	400 Mg, Qd		Not Reported
Rituxan	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	1 G, Bid		Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	15400431	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083976		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Metformin Hydrochloride			S	Unknown	500 Mg, Bid		Bristol Myers Squibb
	Desoximetasone			S	Unknown			Not Reported
	Docosahexaenoic Acid;Eicosapentaenoic Acid			C	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Altace			C	Unknown	5 Mg, Qd		Not Reported
	Asa			C	Unknown	81 Mg, Qd		Not Reported
	Folic Acid			C	Unknown	1 Df, Unk		Not Reported
	Methotrexate			C	Oral	15 Mg, Qd		Not Reported
	Omega 3 [Fish Oil;Tocopherol]			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown	20 Mg, Qd		Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported
	Vitamin D3			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	15899841	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019048311		43 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Corona Virus Infection; Drug Ineffective; Immunodeficiency; Nasal Congestion; Pain	Flector			S	Transdermal	1 Patch To Skin, Twice A Day		Pfizer
	Flector			S				Pfizer
	Diclofenac Sodium			S	Oral	Unk		Not Reported
	Oxymorphone			S		Unk		Not Reported
	Oxycodone			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Pennsaid			S		Unk		Not Reported
	Voltaren [Diclofenac Sodium]			S		Unk		Not Reported
	Cbd			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	15978351	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013839		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Cataract; Drug Ineffective; Laboratory Test Abnormal; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Celebrex			S	Oral	200 Milligram, Q12h		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Q12h	Not Reported
	Arava	C	Unknown	20 Milligram, Qd	Not Reported
	Xeljanz	S	Oral	5 Milligram, Q12h	Not Reported
	Rituximab	S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	16108792	EXPEDITED (15-DAY)		HO, LT	PHHY2019CA062642			Male	CAN

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

	Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine	S				Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	16153117	EXPEDITED (15-DAY)		OT	CA-COLGATE PALMOLIVE COMPANY-20190300924			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State; Contraindicated Product Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Chlorhexidine Unspecified			S		Unk		Colgate
	Periogard Alcohol Free Rinse			S	Buccal	Unk		Colgate
	Chlorhexidine Gluconate Unspecified			S		Unk		Not Reported
	Chlorhexidine Gluconate Unspecified			S		Unk		Not Reported
	Periogard Unspecified			S		Unk		Colgate
	Acetaminophen			S		Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg; 4 Every 1 Week		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg; 4 Every 1 Week		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg, 1x/Month		Not Reported
	Actemra			S		Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg, 1x/Month		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Mg, 1 Every 4 Week(S)		Not Reported

Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, 1 Every 4 Week(S)	Not Reported
Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, 1x/Month	Not Reported
Actemra	S	Intravenous (not otherwise specified)	728.0 Mg, 1x/Month	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Simponi	S	Periarticular	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Enbrel	S		Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Methotrexate	S		Unk	Not Reported
Leflunomide	S			Not Reported
Oxycodone Terephthalate	S		Unk	Not Reported
Sulfamethoxazole;Trimethoprim	S		Unk	Not Reported
Oxycodone Hydrochloride	S		Unk	Not Reported
Sulfamethoxazole	S			Not Reported
Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol	S		Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Oxycodone;Paracetamol	S		Unk	Not Reported
Oxycodone;Paracetamol	S		Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Abatacept	S	Intravenous (not otherwise specified)		Not Reported
Methotrexate Sodium	S		Unk	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Oxycodone	S		Unk	Not Reported
Oxycodone	S		Unk	Not Reported

Apo-Acetaminophen	S			Not Reported
Oxycodone Hydrochloride;Paracetamol	S			Not Reported
Arava	C	Oral	20 Mg, 1x/Day	Not Reported
Arava	C		Unk	Not Reported
Pantoloc [Pantoprazole]	C		Unk	Not Reported
Desogestrel + Etinilestradiol	C		Unk	Not Reported
Pantoprazole Sodium	C		Unk	Not Reported
Pantoprazole Sodium	C		Unk	Not Reported
Ibuprofen	C		Unk	Not Reported
Prednisone	C	Oral	7.5 Mg 1x/Day	Not Reported
Prednisone	C	Oral	Unk, 1x/Day	Not Reported
Prednisone	C		Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	C		10 Mg, 2x/Day	Not Reported
Reactine [Cetirizine Hydrochloride]	C		Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C			Not Reported
Cetirizine Dihydrochloride	C		Unk	Not Reported
Paracetamol	C			Not Reported
Hydroxychloroquine Sulfate	C		400 Mg, 1x/Day	Not Reported
Paracetamol Codeine	C			Not Reported
Tylenol [Paracetamol]	C		Unk	Not Reported
Cetirizine	C			Not Reported
Tylenol With Codeine	C			Not Reported
Pantoprazole	C		Unk	Not Reported
Hydroxychloroquine Phosphate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	16889106	EXPEDITED (15-DAY)		OT	CA-SA-2019SA271272			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug	Arava			S	Unknown			Sanofi

Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil		S	Unknown	Unk Unk, Unk	Sanofi
	Methotrexate		S	Unknown	Unk Unk, Unk	Not Reported
	Xeljanz		S	Unknown	Unk Unk, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17064857	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190827902		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Gastritis; Headache; Nausea; Pain; Platelet Count Increased; Systemic Lupus Erythematosus	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Oral	Dose Doubled In Jan-2020		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17335679	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-HORIZON-PRE-0036-2020			Female	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Growth Restriction; Maternal Exposure During Pregnancy; No Adverse Event; Oligohydramnios; Premature Baby	Prednisone			S	Transplacental	Unk		Not Reported
	Omeprazole			S		Unk		Not Reported
	Bisulepin			S	Transplacental	Unk		Not Reported
	Aminomethylbenzoic Acid			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Vitamin D [Colecalciferol]			S	Transplacental	Unk		Not Reported
	Folic Acid			S	Transplacental	Unk		Not Reported
	Cefixime			S	Transplacental	Unk		Not Reported
	Paracetamol			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Privigen			S	Transplacental	Unk		Not Reported

Privigen	S	Transplacental	Unk		Not Reported
Ornidazole	S	Transplacental	Unk		Not Reported
Magnesium Lactate	S	Transplacental	Unk		Not Reported
Vitamin K Nos	S	Transplacental	Unk		Not Reported
Bisoprolol Fumarate	S	Transplacental	Unk		Not Reported
Vulmizolin	S	Transplacental	Unk		Not Reported
Vitamin B Complex	S		Unk		Not Reported
Calcium Carbonate	S	Transplacental	Unk		Not Reported
Potassium Chloride	S	Transplacental	Unk		Not Reported
Fluconazole	S	Transplacental	Unk		Not Reported
Penicillin G [Benzylpenicillin Sodium]	S	Transplacental	Unk		Not Reported
Flebogamma Dif [Immunoglobulin Human Normal]	S	Transplacental	Unk		Not Reported
Hydrocortisone	S	Transplacental	Unk		Not Reported
Methylprednisolone	S	Transplacental	Unk		Not Reported
Methylprednisolone	S	Transplacental	Unk		Not Reported
Nadroparine	S	Transplacental	Unk		Not Reported
Etamsylate	S	Transplacental	Unk		Not Reported
Cefotaxime	S	Transplacental	Unk		Not Reported
Cefotaxime	S	Transplacental	Unk		Not Reported
Metoprolol Tartrate	S	Transplacental	Unk		Not Reported
Albumin	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17530878	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202002001243			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Hypersensitivity; Nausea; Rheumatoid Arthritis;	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

Urticaria; Vertigo; Weight Decreased	Methotrexate		S	Unknown	Unk	Not Reported
	Celebrex		C		Unk	Not Reported
	Tylenol		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17552501	EXPEDITED (15-DAY)		OT	GB-CELLTRION INC.-2020GB020489			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dermatomyositis; Disease Progression; Product Use In Unapproved Indication; Pseudomonas Infection; Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Mycophenolate			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	60 Milligram		Not Reported
	Prednisolone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17570310	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068426			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17578248	EXPEDITED (15-DAY)		HO, LT, OT	PT-MYLANLABS-2020M1031689		50 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Tamponade; Cardiogenic Shock; Cardiomegaly; Concomitant Disease Aggravated; Dyspnoea Exertional; Dyspnoea Paroxysmal Nocturnal; Electrocardiogram Qrs Complex Abnormal; Heart Sounds Abnormal; Oedema Peripheral; Pericardial Effusion; Pericardiotomy; Pleural Effusion; Prohormone Brain Natriuretic Peptide Increased; Rales; Serositis	Bosentan			S	Oral	250 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	5 Mg, Qd		Mylan
	Mycophenolate Mofetil			S	Unknown	2.5 G, Qd		Mylan
	Remodulin			S	Subcutaneous	0.046 Mg, Q1hour		Mylan
	Remodulin			S	Subcutaneous	0.046 Mg, Q1hour		Mylan
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Mylan
	Riociguat			C	Unknown	6 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17578988	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024680			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588707	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025879		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Stress	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Mefenamic Acid			C	Unknown			Not Reported
	Prednisone			C	Oral	6 Milligram, Qd		Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588868	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0830		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Contraindicated Product Administered; Drug Ineffective; Gastrointestinal Disorder;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Hepatic Enzyme Increased; Ileus; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapy Non-Responder	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo Hydroxyquine	S	Unknown	Not Reported
	Apo-Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588873	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1542			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588875	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1543			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588876	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1554			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17588922	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1533			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17589340	EXPEDITED (15-DAY)		HO, OT	US-ORION CORPORATION ORION PHARMA-20_00008751		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Bartonella Test Positive; Cat Scratch Disease; Device Dislocation;	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

Pneumonia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590071	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-241501		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Microsporidia Infection	Hydroxychloroquine			S	Unknown	Unk		Sun
	Hydroxychloroquine			S				Sun
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590112	EXPEDITED (15-DAY)		HO	CA-SA-2020SA075289			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Off Label Use	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd (1 Everyday)		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd, Tablet (1 Every 1 Day)		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw (1 Every 1 Weeks)		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	80 Mg/Kg		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow., Solution Subcutaneous		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Orencia			S				Not Reported
	Orencia			S	Unknown			Not Reported

	Orencia	S				Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590113	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075134			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Joint Swelling; Pain; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Atorvastatin Calcium			S				Not Reported
	Leflunomide			S				Sanofi
	Pregabalin			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Trichlormethiazide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590114	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA075343			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Leflunomide			S		10 Mg		Sanofi
	Leflunomide			S		10 Mg		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S		15 Mg		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Sulfasalazine			S	Oral	1 G		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported

Humira	S	Subcutaneous			Not Reported
Orencia	S	Subcutaneous	125 Mg, Qw		Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
Rituximab	S		Unk		Not Reported
Prednisone	C		10 Mg		Not Reported
Prednisone	C		5 Unk		Not Reported
Simponi	C	Subcutaneous			Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590131	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009143		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fatigue; Gait Disturbance; Wrist Surgery	Meloxicam			S	Unknown	Unk		Apotex
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590361	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075141			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S				Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Golimumab			S				Not Reported
	Humira			S				Not Reported
	Infliximab			S				Not Reported

Product Effect Decreased	Otezla	S	Not Reported
	Acetaminophen	C	Not Reported
	Advair	C	Not Reported
	Allopurinol	C	Not Reported
	Atrovent Hfa	C	Not Reported
	Codeine	C	Not Reported
	Cyclobenzaprine Hydrochloride	C	Not Reported
	Dilaudid	C	Not Reported
	Hydromorphone Hydrochloride	C	Not Reported
	Ibuprofen	C	Not Reported
	Leucovorin Calcium	C	Not Reported
	Nexium [Esomeprazole Sodium]	C	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Not Reported
	Sulfasalazine	C	Not Reported
	Ventolin Hfa	C	Not Reported
	Xeljanz	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590363	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076294			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Actemra			S				Not Reported
	Lyrica			S	Oral	150 Mg, Bid		Not Reported
	Acetaminophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590399	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076538		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness;	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Arava			S				Sanofi
	Sodium Aurothiomalate			S		Unk		Not Reported

Rheumatoid Arthritis; Treatment Failure	Enbrel	S		50 Mg, Qw	Not Reported
	Leflunomide	S		Unk	Sanofi
	Methotrexate	S	Oral	25 Mg, Qd	Not Reported
	Myochrysine	S	Intramuscular	25 Mg, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590401	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076268			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590669	EXPEDITED (15-DAY)		OT	US-AMNEAL PHARMACEUTICALS-2020-AMRX-00900		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Toxicity	Cyclophosphamide			S	Unknown	21-Day Cycle, 4 Cycles		Amneal

	Docetaxel	S	Unknown	21-Day Cycle, 4 Cycles	Amneal
	Anastrozole	S	Unknown	21-Day Cycle, 4 Cycles)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	7.1 Mg/Kg Real Body Weight, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17590700	EXPEDITED (15-DAY)		HO	US-GYP-000097		30 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Herpes Simplex; Trichomoniasis	Prednisone			S	Unknown	5 Mg Daily		Geneyork Pharma
	Hydroxychloroquine			S	Unknown	200 Mg Twice Daily		Not Reported
	Metronidazole			S	Oral			Not Reported
	Paracetamol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591184	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026344		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Orencia			S	Endocervical			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591627	DIRECT		HO			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Folliculitis; Oral Disorder; Pharyngeal Disorder; Skin Swelling; Therapy Cessation; Urticaria; Urticaria	Hydroxychloroquine (Plaquenil)			S	Oral			Not Reported
	Pravastatin			C				Not Reported
	Fosomax			C				Not Reported
	Prempro			C				Not Reported
	Premarin			C				Not Reported
	Sipronlactone			C				Not Reported
	Minoxidil			C				Not Reported
	Doxycycline			C				Not Reported
	Omeprazole			C				Not Reported
	Singular			C				Not Reported
	Ventolin			C				Not Reported
	Azelastine			C				Not Reported
	B-Complex			C				Not Reported
	Triple Omega Fish Oil			C				Not Reported
	Calcium			C				Not Reported
	Vit. D-3			C				Not Reported
	Evening Primrose			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591702	EXPEDITED (15-DAY)		OT	NVSC2020CA083830		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant	Methotrexate			S	Unknown	25 Mg, Unknown		Not Reported
	Tacrolimus			S	Oral	2 Mg, Q12h		Novartis
	Tacrolimus			S	Oral	3 Mg, Q12h		Novartis
	Leflunomide			S	Unknown	20 Mg, Unknown		Not Reported
	Neoral			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unknown		Not Reported
	Certolizumab Pegol			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Dysfunction; Transplant Rejection	Enbrel		S	Subcutaneous	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxyquinoline Sulfate		S	Unknown	Unk	Not Reported
	Plaquenil		S	Unknown	Unk	Not Reported
	Rapamune		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine		S	Unknown	1 G, Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591728	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085589		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Remicade	S				Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate	S				Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591840	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026340			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591841	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026360		69 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Orencia			S	Endocervical			Bristol Myers Squibb
	Actemra			S	Unknown	1 Dosage Form		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Calcium			C	Unknown	500 Milligram, Qd		Not Reported

Dorzolamide Hydrochloride/Timolol Maleate	C	Unknown	Unk, Bid		Not Reported
Ergocalciferol	C	Unknown	Unk, Qwk		Not Reported
Estradiol	C	Unknown	0.6 Percent, Tid		Not Reported
Estrogel	C	Unknown	0.6 Percent, Tid		Not Reported
Furosemide	C	Unknown	40 Milligram, Qd		Not Reported
Gravol	C	Unknown			Not Reported
Potassium Chloride	C	Unknown	1500 Milligram, Qd		Not Reported
Valsartan	C	Unknown	320 Milligram, Qd		Not Reported
Xalatan	C	Ophthalmic	50 Microgram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591924	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076466			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	25 Mg, Qw		Not Reported
	Leflunomide			S				Sanofi
	Enbrel			S		50 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591928	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076322			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi

Pregabalin	S	Oral	150 Mg, Bid		Not Reported
Methotrexate	S	Oral	20 Mg, Qw		Not Reported
Actemra	S				Not Reported
Acetaminophen	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591942	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085582			Male	CAN

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

Sulfasalazine	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17591972	NON-EXPEDITED			US-SA-2018SA048629			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Liver Function Test Increased	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S		Unk Unk,Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17592969	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068673		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Leflunomide			S		Unk		Sanofi
	Leflunomide			S				Sanofi
	Hydroxychloroquine			S	Subcutaneous	40 Mg		Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Methotrexate			S		10 Mg		Not Reported
	Kevzara			S				Sanofi
	Sulfasalazine			S				Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 G		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S				Not Reported

	Tofacitinib	S			Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	C		10 Mg	Not Reported
	Rabeprazole Sodium	C		20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17593152	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17594000	EXPEDITED (15-DAY)		OT	NVSC2020CA083912		74 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity;	Neoral			S	Unknown	125 Mg, Bid, (2 Every 1 Day)		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	1 G, Unknown		Not Reported
	Arava			S	Unknown	20 Mg, Qd, (Every 1 Day)		Not Reported
	Azathioprine Sodium			S	Unknown	150 Mg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw, (1 Every 1		Not Reported

Pruritus; Rash; Squamous Cell Carcinoma Of Skin; Treatment Failure				Week)	
	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Imuran	S	Unknown	150 Mg, Tid, (3 Evey 1 Day)	Not Reported
	Methotrexate	S	Oral	1 Df, Qw, (1 Every 1 Week)	Not Reported
	Plaquenil	S	Unknown	200 Mg, Bid (2 Every 1 Day)	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid, (2 Every 1 Day)	Not Reported
	Citalopram Hydrobromide	C	Unknown	40 Mg	Not Reported
	Citalopram Hydrobromide	C	Unknown	40 Mg, Qd (Every 1 Day)	Not Reported
	Citalopram Hydrobromide	C	Unknown	1 Df, Qw	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd (Every 1 Day)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17594370	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085524		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Novartis
	Ilaris			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported

Humira	S	Subcutaneous	Unk		Not Reported
Hidroxicloroquina	S	Unknown	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Unknown			Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17594417	EXPEDITED (15-DAY)		DE, HO	NVSC2020CA085101		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Subcutaneous			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported

Remicade	S	Unknown		Not Reported
Remicade	S			Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	17594574	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022677			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Colonic Abscess; Drug Ineffective; Pruritus	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	350 Milligram		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	40 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Enbrel			C	Unknown	50 Milligram		Not Reported
	Gold			C	Intramuscular	50 Milligram		Not Reported
	Leflunomide			C	Unknown	20 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2020	17431505	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1186390			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance	Hydroxychloroquine			S	Unknown			Teva

	Trametinib	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2020	17595044	EXPEDITED (15-DAY)		OT	IT-ACCORD-177503		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S				Accord
	Dabigatran			S	Oral			Not Reported
	Daparox			S				Not Reported
	Lamictal			S				Not Reported
	Plaquenil			S				Not Reported
	Valium			S				Not Reported
	Sotalol			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2020	17595150	NON-EXPEDITED			NVSC2020US086178			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2020	17597821	DIRECT		DS			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Eye Disorder; Vascular Device User	Hydroxychloroquine	Y		S	Oral	Quantity:1 Tablet(S);		Unknown
	Orencia	Y		S	Intramuscular	Quantity:1 Injection(S);Other Frequency:Once A Week;		Er Squibb
	Heart Meds			C				Not Reported
	Diabetes Meds			C				Not Reported
	Inhalers			C				Not Reported
	Med For Migraines			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2020	17598592	DIRECT		DS			39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Joint Stiffness; Manufacturing Materials Issue; Product Complaint; Product Substitution Issue; Therapy Non-Responder	Hydroxychloroquine 200mg Tab			S				Dr Reddys
	Omeprazole			C				Not Reported
	Hydroxychloroquinine			C				Not Reported
	Clarinex			C				Not Reported
	Turmeric			C				Not Reported
	Iron			C				Not Reported
	Mvi			C				Not Reported
	Vitamind3			C				Not Reported
	Aleve			C				Not Reported
	Tylenol			C				Not Reported
	Pseudoephedrine			C				Not Reported
	Guaifenesin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	12351402	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2016GSK063971		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Voltaren			S	Unknown	Unk		Glaxosmithkline
	Cortisone			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Diclofenac			S		Unk		Not Reported
	Desoximetasone			S		Unk		Not Reported
	Diclofenac Potassium			S		Unk		Not Reported
	Remicade			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	12764755	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076425			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Disability; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileus; Intestinal Obstruction; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	12767211	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-015691		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	10 Milligram, Bid		Not Reported
	Xeljanz			C	Subcutaneous	Unk		Not Reported
	Desoximetasone			C	Oral	10 Milligram, Qd		Not Reported
	Desoximetasone			C	Oral	5 Milligram 2 Every 1 Day		Not Reported
	Zostavax			C	Subcutaneous	Unk		Not Reported
	Cortisone			C	Oral	10 Milligram, Qd		Not Reported
	Diclofenac			C	Subcutaneous	100 Milligram, Qd		Not Reported
	Voltaren Acti			C	Unknown	100 Milligram, Qd		Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported

	Desoximetasone	C	Subcutaneous		Not Reported
	Diclofenac	C	Oral	50 Milligram, Bid	Not Reported
	Diclofenac	C	Oral	100 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	12771269	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076855		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasis; Synovitis; Tooth Loss	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Diclofenac [Diclofenac Sodium]			C	Subcutaneous	100 Milligram		Not Reported

Diclofenac [Diclofenac Sodium]	C	Oral	5 Milligram, Bid		Not Reported
Cortisone	C	Oral	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Xeljanz	C	Oral	10 Milligram, Bid		Not Reported
Cortisone Acetate	C	Subcutaneous	Unk		Not Reported
Desoximetasone	C	Oral	5 Milligram, Bid		Not Reported
Desoximetasone	C	Oral	10 Milligram, Qd		Not Reported
Desoximetasone	C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	13251617	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006643			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported
	Zostavax			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Desoximetasone			C	Oral	Unk		Not Reported

Diclofenac	C	Unknown	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	13502224	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1253		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Haematoma; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naprosyn			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	14547629	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-040466		28 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Sinusitis; Anaphylactic Shock; Anxiety; Bronchitis; Depression; Device Malfunction; Electric Shock; Faeces Soft; Fatigue; Gait Disturbance; Headache; Influenza Like Illness; Long Qt Syndrome; Mouth Ulceration; Nausea; Off Label Use; Pain; Productive Cough; Pyrexia; Seasonal Allergy; Secretion Discharge; Sinusitis; Tongue Ulceration; Upper	Abatacept			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Pantoloc [Pantoprazole]			C	Unknown	Unk		Not Reported
	Leucovorin [Folinic Acid]			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Ativan			C	Unknown	Unk		Not Reported

Respiratory Tract Infection
Bacterial

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	14918934	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-043916		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Mg, Qwk		Bristol Myers Squibb
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Gram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Tid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	2000 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2000 Mg, Unk		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	2000 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Actemra	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Tofacitinib	C	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Q2wk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	15551969	EXPEDITED (15-DAY)		OT	PHHY2018CA135990		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk (Solution)		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Apremilast			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Infliximab			C	Unknown	Unk		Not Reported
	Penicillin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16387991	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029881		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated;	Lisinopril Tablet			S	Unknown	Unk		Aurobindo

Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Folic Acid	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	20 Milligram, Every Week	Not Reported
	Plaquenil	S	Oral	200 Milligram, Once A Day	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Once A Day	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Tecta	S	Oral	Unk	Not Reported
	Voltaren Sr	S	Oral	75 Milligram,As Required	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Two Times A Day	Not Reported
	Depo-Medrol	C	Intramuscular	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16388028	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029853		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Diclofenac Potassium			S	Oral	75 Milligram		Not Reported
	Diclofenac Potassium			S	Oral	75 Milligram, Two Times A Day		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Two Times A Day		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Tecta			S	Oral	Unk		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Two Times A Day		Not Reported

	Depo-Medrol	C	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16778008	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-025000		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac Sodium			S	Unknown			Not Reported
	Cortisone			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Topicort			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Atasol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16792776	EXPEDITED (15-DAY)		OT	PHHY2019CA209333			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cellulitis; Drug Ineffective; Infection	Cosentyx			S	Unknown	150 Mg, Qw		Novartis
	Humira			S	Subcutaneous	40 Mg, Q2w		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Arava			C	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			C	Oral	1 Df, Qw		Not Reported
	Prednisone			C	Oral	1 Df, Qd		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Q12h		Not Reported

	Xeljanz	C	Oral	5 Mg, Q12h		Not Reported
	Xeljanz	C	Oral	5 Mg, Q8h		Not Reported
	Xeljanz	C	Oral	5 Mg, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16811263	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20190905771			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Paracetamol			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Tylenol Arthritis Pain 8h			S	Unknown			Not Reported
	Paracetamol/Diphenhydramine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Hydroxychloroquine /00072603/		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Sulfasalazine	S	Oral	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Paracetamol/Codeine Phosphate	C	Unknown	Not Reported
	Oros Hydromorphone Hcl	C	Unknown	Not Reported
	Tylenol W/ Codeine No. 3	C	Unknown	Not Reported
	Celebrex	C	Oral	Not Reported
	Celecoxib	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	16881443	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-28961		66 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Pneumonia; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Remicade			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Single-Use Pre-		Not Reported

				Filled Syringe	
	Cimzia	S	Unknown	Unknown, Single-Use Pre-Filled Syringe	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
	Xeljanz	S	Oral		Not Reported
	Lidocaine Hydrochloride	S	Subcutaneous	Unknown, Aerosol	Not Reported
	Lidocaine Hydrochloride	S	Subcutaneous	Unknown	Not Reported
	Cephalexin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17416777	EXPEDITED (15-DAY)		OT	US-SA-2020SA038806		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pleural Effusion	Arava			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17422945	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010439		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported

Apo-Leflunomide	S	Unknown	Unk	Not Reported
Ciclosporin	S	Unknown		Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate	C	Subcutaneous	20 Milligram	Not Reported
Methotrexate	C	Subcutaneous	20 Milligram	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral		Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17467057	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-008069		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alanine Aminotransferase Abnormal; Alanine Aminotransferase	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	Unk		Not Reported

Increased; Arthralgia; Arthritis; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; Decreased Appetite; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Intolerance; Enthesopathy; Erythema; Fatigue; Fear Of Injection; General Physical Health Deterioration; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nausea; Pain; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment	Apo Ibuprofen	S	Oral	600 Milligram	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apremilast	S	Oral	30 Milligram, Bid	Not Reported
	Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
	Apremilast	S	Unknown		Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Celebrex	S	Oral	200 Milligram, Bid	Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Ciclosporin	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Codeine	S	Unknown		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Cyclosporin	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Times/Wk	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Golimumab	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Ibuprofen	S	Oral	600 Milligram, Every 1 Days	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	400 Milligram	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral	Unk, Qwk	Not Reported
	Motrin Children	S	Oral	600 Milligram	Not Reported
	Motrin Children	S	Unknown	6 Dosage Form, Qd	Not Reported
	Motrin Children	S	Oral	600 Milligram, Qd	Not Reported
	Motrin Children	S	Oral	Unk Milligram, Qd	Not Reported

Failure; Ulcer; Urticaria	Otezla	S	Oral	30 Milligram, Bid	Not Reported
	Otezla	S	Unknown		Not Reported
	Otezla	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Ustekinumab	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Etanercept	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Apo-Cyclosporine	S	Oral	Unk	Not Reported
	Acide Folique	C	Unknown		Not Reported
	Actonel	C	Oral	35 Milligram, Qwk	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
	Colchicine	C	Unknown	0.6 Milligram	Not Reported
	Dexilant	C	Unknown	Unk	Not Reported
	Febuxostat	C	Unknown	80 Milligram, Bid	Not Reported

Folic Acid	C	Unknown	Unk		Not Reported
Gravol	C	Unknown			Not Reported
Methotrexate Sodium	C	Oral	Unk, Qwk		Not Reported
Mogadon	C	Unknown	5 Milligram		Not Reported
Naproxen	C	Unknown	500 Milligram		Not Reported
Nitrazepam	C	Oral	Unk		Not Reported
Nitrazepam	C	Unknown	5 Milligram		Not Reported
Oxycodone	C	Unknown	10 Milligram		Not Reported
Oxycodone	C	Unknown	40 Milligram		Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Milligram		Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram		Not Reported
Oxyneo	C	Unknown	10 Milligram		Not Reported
Oxyneo	C	Unknown	40 Milligram		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Uloric	C	Oral	8 Milligram, Bid		Not Reported
Uloric	C	Unknown	Unk		Not Reported
Uloric	C	Unknown	80 Milligram, Bid		Not Reported
Vitamin D3	C	Oral	200 International Unit		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17493046	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-238891		29 YR	Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cerebral Infarction; Cerebrovascular Accident; Transient Ischaemic Attack; Treatment Failure	Atorvastatin			S	Unknown	Unk		Sun
	Warfarin			S	Unknown	Unk		Taro
	Clopidogrel			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17581926	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA083381		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Ilaris			S	Unknown			Novartis
	Ilaris			S				Novartis
	Ilaris			S	Subcutaneous			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Rituximab			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S				Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

	Sulfasalazine	S	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17584606	EXPEDITED (15-DAY)		OT	NVSC2020US082743		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Microsporidia Infection; Product Use In Unapproved Indication	Mycophenolate Mofetil			S	Unknown	3 G, Qd		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596866	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-015777		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S	Unknown	Unk		Aurobindo
	Dabigatran Etexilate			S	Oral	300 Milligram, Once A Day		Not Reported
	Daparox			S	Unknown	Unk		Not Reported
	Lamictal			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Valium			S	Unknown	Unk		Not Reported
	Sotalol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596878	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068447			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Arava			S	Oral	20 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine			S	Oral	600 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	20 Mg, Qd		Not Reported

	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
	Folic Acid	C		1 Df, Qw	Not Reported
	Xeljanz	C		5 Mg, Bid	Not Reported
	Xeljanz	C	Oral	5 Mg, Qd	Not Reported
	Prednisone	C			Not Reported
	Simponi	C	Subcutaneous	Solution	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596898	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068448			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Arava			S		Unk		Sanofi
	Desoximetasone			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Folic Acid			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cetrizine			S		Unk		Not Reported
	Cimzia			S		Unk		Not Reported
	Etanercept			S		Unk		Not Reported
	Fosamax			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596904	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-241793		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	8.22 Milligram/Kilogram		Sun

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596948	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068521		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Arava			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown	20.0 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown	Dosage Form: Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Rituxan			S	Unknown	Dosage Form: Solution Intravenous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596953	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068456			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Pulmonary	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			S		15 Mg, Qw		Not Reported

Toxicity; Therapeutic Product Effect Incomplete	Plaquenil	S	200 Mg, Bid		Sanofi
	Actemra	S	567 Mg, Qm		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Celebrex	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596954	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068451			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Leflunomide			S				Sanofi
	Hydroxychloroquine			S		400 Mg, Qd		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596980	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1580			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596997	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068694			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Leflunomide			S		10 Mg		Sanofi
	Leflunomide			S		Unk, Qd		Sanofi
	Plaquenil			S		200 Mg, Bid		Sanofi
	Cosentyx			S		150 Mg, Q4w		Not Reported
	Humira			S		400 Mg In 7 Years		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Prednisone			S				Not Reported
	Cymbalta			C		60 Mg, Qd		Not Reported
	Esomeprazole Magnesium;Naproxen			C	Oral			Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596998	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068558		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Sanofi
	Mefenamic Acid			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported

Enbrel	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Orencia	S		Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Tocilizumab	S		Unk		Not Reported
Xeljanz	S	Oral	10 Mg, Qd		Not Reported
Synthroid	C		Unk		Not Reported
Rabeprazole Sodium	C		Unk		Not Reported
Folic Acid	C		Unk		Not Reported
Metformin	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17596999	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068621			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Arava			S		Unk		Sanofi
	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Plaquenil			S	Unknown	200 Mg, Qd		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Enbrel			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Advil [Ibuprofen]			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported

	Ketorolac	C		Unk	Not Reported
	Methotrexate	C	Unknown	20 Mg, Qw	Not Reported
	Naproxen	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597002	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068605			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis; Treatment Failure	Arava			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597003	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068651			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S		20 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		25 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Methotrexate			S		20 Mg, Qow		Not Reported
	Orencia			S				Not Reported
	Plaquenil			S		200 Mg, Bid		Sanofi
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Bupropion			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597009	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068702			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			C		Unk		Not Reported
	Methotrexate			C		Unk Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597010	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068717		24 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Leflunomide			S		Unk		Sanofi
	Allopurinol			S		Unk		Not Reported
	Folic Acid			S				Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Prednisone			S		Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Naproxen			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Oxycodone Hydrochloride			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Ciclosporin			S				Not Reported

Medroxyprogesterone Acetate	S	Unk		Not Reported
Etanercept	S	25 Mg ,Qw		Not Reported
Infliximab	S	400 Mg		Not Reported
Rituximab	S	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597077	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1212448		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Headache; Palpitations	Risedronate Monosodique			S	Oral	35 Mg		Teva
	Plaquenil			S	Oral	1 Dosageform		Not Reported
	Cortancyl 20 Mg, Comprime			S	Oral			Not Reported
	Pantoprazole			C				Not Reported
	Izalgi 500 Mg/25 Mg, Gelule			C		500 Mg/25 Mg,		Not Reported
	Levothyrox 75 Microgrammes, Comprime Secable			C				Not Reported
	Diffu K, Gelule			C				Not Reported
	Atorvastatine			C				Not Reported
	Clopidogrel (Chlorhydrate De)			C				Not Reported
	Procoralan 5 Mg, Comprime Pellicule			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597242	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025396		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Bone Disorder; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cefazolin			S	Intramuscular			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1		Not Reported

				Day	
	Leflunomide	S	Oral	10 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Arava	C	Unknown		Not Reported
	Naproxen	C	Unknown	500 Milligram, 2 Every 1 Day	Not Reported
	Viread	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, 2 Every 1 Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597342	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068726		80 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Balance Disorder; Cardiac Disorder; Coronary Artery Bypass; Dermatitis Allergic; Drug Hypersensitivity; Foot Deformity; Hand Deformity; Infection; Irritable Bowel Syndrome; Lung Neoplasm Malignant; Pain In Extremity; Surgery; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Toe Amputation	Arava			S				Sanofi
	Gold Bond			S				Sanofi
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	10 Mg		Not Reported
	Plaquenil			S				Sanofi
	Arnica Montana			C				Not Reported
	Asa			C				Not Reported
	Calcium			C				Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597343	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068740			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis; Rheumatoid Arthritis	Leflunomide			S		1 Df (1 Every 1 Days)		Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S		500 Mg, Bid		Not Reported
	Xeljanz			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Lyrica			C				Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597347	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068725			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthrodesis; Drug Ineffective; Empyema; Foot Deformity; Hand Deformity; Joint Effusion; Joint Stiffness; Limb Operation; Musculoskeletal Stiffness; Nodule; Pneumonia; Rheumatoid Arthritis; Scar; Toe Operation	Leflunomide			S		20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Urethral	20 Mg, Qd		Sanofi
	Ibuprofen			S	Unknown	400 Mg		Not Reported
	Methotrexate			S		25 Mg, Qw		Not Reported
	Methotrexate			S		25 Mg, Qw		Not Reported
	Methotrexate			S		25 Mg, Qw		Not Reported
	Sulfasalazine			S		2000 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Calcium			C		1200 Mg		Not Reported
	Ergocalciferol			C		2000 Iu, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597348	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068745		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Diarrhoea; Dyspepsia; Nodule; Osteoarthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		25 Mg, Qw		Not Reported
	Sulfasalazine			S		1000 Mg, Bid		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597350	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068748			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S		Unk		Sanofi
	Bacitracin			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Neomycin Sulfate			S		Unk		Not Reported
	Polymyxin B Sulfate			S		Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Prednisone			C	Intramuscular			Not Reported
	Xeljanz			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597351	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068446		54 YR	Female	CAN

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

Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Arava	S		Unk Unk, Qd	Sanofi
	Meloxicam	S		Unk	Not Reported
	Methotrexate	S			Not Reported
	Plaquenil	S			Sanofi
	Prednisone	S		5 Mg, Qd	Not Reported
	Sulfasalazine	S			Not Reported
	Paracetamol	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597410	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068817			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Fatigue; Hand Deformity; Infection; Pain; Therapy Non-Responder	Leflunomide			S	Unknown	20.0 Mg, Qd		Sanofi
	Celecoxib			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Mg, Qd		Sanofi
	Toradol			S	Unknown			Not Reported
	Methotrexate			C	Unknown	25.0 Mg, Qw		Not Reported
	Sulfasalazine			C		2.0 G, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597412	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068814		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Pulmonary Fibrosis; Treatment Failure	Arava			S		Unk		Sanofi
	Desoximetasone			S	Oral	Unk		Sanofi
	Desoximetasone			S		Unk		Sanofi
	Leflunomide			S		1 Df, Qd		Sanofi
	Plaquenil			S		Unk		Sanofi
	Prednisone			S		Unk		Not Reported

	Hydroxychloroquine	S		200 Mg, Qd	Sanofi
	Hydroxychloroquine	S			Sanofi
	Methotrexate	S		Unk	Not Reported
	Methotrexate	S			Not Reported
	Enbrel	S		1 Df, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597474	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068888			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Joint Stiffness; Joint Swelling; Pruritus; Psoriasis	Leflunomide			S		1 Df, Qd		Sanofi
	Plaquenil			S		300 Mg, Qd		Sanofi
	Cimzia			S	Subcutaneous	Unk (Subcutaneous Solution)		Not Reported
	Alendronate Sodium			C	Oral	70 Mg		Not Reported
	Atenolol			C		3 Df		Not Reported
	Certolizumab Pegol			C	Subcutaneous	Unk		Not Reported
	Chlordiazepoxide;Clidinium Bromide			C	Oral	Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Oral	40 Mg		Not Reported
	Hydrochlorothiazide			C	Oral	25 Mg, Qd		Not Reported
	Lorazepam			C	Oral	1 Mg, Qd		Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C	Oral	Unk		Not Reported
	Trimebutine			C		1 Df, Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597475	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068908			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Steatosis; Interstitial Lung Disease; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	15 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow, Solution Subcutaneous		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597476	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068846			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Cimzia			S	Subcutaneous	200 Mg		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported

	Xeljanz	C	11 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597487	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068893			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Finger Deformity; Hand Deformity; Peripheral Swelling; Peripheral Swelling; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597495	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA069320		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine			S				Sanofi
	Naproxen Sodium			S		Unk		Not Reported
	Prednisone			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Orencia			S				Not Reported
	Xeljanz			S				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597496	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069110			Female	CAN

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

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide	S				Sanofi
	Actemra	S	Unknown			Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous	Total Daily Dose 40 Mg		Not Reported
	Hydroxychloroquine	S				Sanofi
	Hydroxychloroquine Sulfate	S	Unknown			Sanofi
	Methotrexate	S	Unknown			Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597501	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069115			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Ill-Defined Disorder; Neuropathy Peripheral; Stomatitis	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Sulfasalazine			S				Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597502	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA069085		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional	Leflunomide			S		Unk		Sanofi
	Actemra			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate	S				Not Reported
	Naproxen	S				Not Reported
	Naproxen Sodium	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	S				Not Reported
	Prednisone Acetate	S				Not Reported
	Tocilizumab	S				Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Folic Acid	C		Unk		Not Reported
	Hydroxychloroquine Sulphate	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597503	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069113		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Peripheral Swelling; Rheumatoid Arthritis; Stress	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597507	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069114			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Intolerance; Finger Deformity; Foot Deformity;	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Humira			S	Subcutaneous	40 Mg 1 Every 2 Weeks		Not Reported

Gait Disturbance; Infection; Pancytopenia	Methotrexate	S	Oral	7.5 Mg 1 Every 1 Weeks	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Arava	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597724	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085875			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism	Ilaris			S	Unknown			Novartis
	Ilaris			S				Novartis
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Actemra			S	Unknown			Not Reported

	Actemra			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17597887	EXPEDITED (15-DAY)		HO	CA-SA-2020SA069360		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Naproxen Sodium			S				Not Reported
	Prednisone			S				Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported
	Actemra			S				Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17598089	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2020050982		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac Sodium			S	Oral	75 Mg, Bid		Glaxosmithkline
	Diclofenac Sodium			S	Oral	75 Mg, Bid		Glaxosmithkline
	Diclofenac Potassium			S	Oral	75 Mg, Prn		Glaxosmithkline
	Pantoprazole			S	Unknown	Unk		Glaxosmithkline
	Pantoprazole			S	Oral	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	Unk		Glaxosmithkline
	Voltaren (Diclofenac Sodium)			S	Oral	75 Mg, Bid		Glaxosmithkline
	Apo - Diclo (Diclofenac Sodium)			S	Oral	75 Mg, Bid		Not Reported
	Apo Lisinopril			S	Oral	Unk		Not Reported

Hydroxychloroquine Sulfate	S	Oral	200 Mg, Qd		Not Reported
Lisinopril	S	Unknown	Unk		Not Reported
Lisinopril Dihydrate	S	Unknown	Unk		Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Qw		Not Reported
Sodium Aurothiomalate	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Oral	2 G, Qd		Not Reported
Synthroid	S	Oral	Unk		Not Reported
Tecta	S	Oral	Unk		Not Reported
Xeljanz	S	Oral	10 Mg, Qd		Not Reported
Gold	C	Unknown	Unk		Not Reported
Depo-Medrol	C	Intramuscular	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17598822	EXPEDITED (15-DAY)		LT	NVSC2020CA085528		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Rituximab			S	Intravenous (not otherwise specified)			Novartis
	Leflunomide			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Orencia	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Sodium Aurothiomalate	S	Unknown			Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unknown		Not Reported
Urelumab	C	Unknown			Not Reported
Rituximab	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17598887	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Off Label Use; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17599129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571299		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Subcutaneous	Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17599148	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2020126926			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Drug Ineffective; Dry Skin; Emphysema; Hypoaesthesia; Joint Injury; Joint Swelling; Nausea; Off Label Use; Paraesthesia; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Nodule	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk (10mg To 15mg)		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Oral	15 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	30 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	2 G, 1x/Day		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	2 G, 1x/Day		Pfizer
	Sulfasalazine			S	Unknown	4 G, 1x/Day		Pfizer
	Sulfasalazine			S	Unknown	3 G, 1x/Day		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

	Cosentyx	S	Intramuscular	300 Mg, Unk	Not Reported
	Cosentyx	S	Oral	40 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
	Leflunomide	C		20 Mg, Unk	Not Reported
	Leflunomide	C		10 Mg, Unk	Not Reported
	Leflunomide	C		20 Mg, Unk	Not Reported
	Tocilizumab	C	Subcutaneous	162 Mg, Weekly	Not Reported
	Abatacept	C	Subcutaneous	125 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17599397	NON-EXPEDITED		OT	US-APPCO PHARMA LLC-2082107			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome; Suspected Product Contamination	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600334	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026570		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Unknown			Not Reported
Actemra	S	Unknown			Not Reported
Arava	S	Unknown			Not Reported
Enbrel	S	Unknown			Not Reported
Humira	S	Subcutaneous	40 Milligram		Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Piroxicam	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600344	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076298		80 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Leflunomide			S	Unknown	Tablet		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S				Not Reported
	Allopurinol			C	Unknown	200 Mg, Qd (1 Every 1 Day)		Not Reported
	Prednisone			C		5 Mg, Bid		Not Reported
	Prednisone			C		10 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600442	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA076641			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Hydroxychloroquine Sulfate			S	Oral	5 Mg, Qd		Sanofi
	Naproxen			S		Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg Bid		Not Reported
	Prednisone			S	Oral	5 Mg Bid		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Naproxen Sodium			S		Unk		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S		Unk (Suspension Intra-Articular)		Sanofi
	Triamcinolone Acetonide			S				Sanofi
	Triamcinolone Acetonide			S				Sanofi
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qow		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Qd		Not Reported
	Immunoglobulins Nos			S	Intravenous (not otherwise specified)	70 G		Not Reported
	Infliximab			S		5 Mg		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported
	Triamcinolone			S	Subcutaneous	25 Mg, Qow		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600443	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-SA-2020SA076630		12 YR	Female	CAN

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

Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use Issue; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Hydroxychloroquine Sulfate	S	Oral	5 Mg/Kg, Qd	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	5 Mg Qd	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Naproxen	S	Oral	5 Mg, Qd	Not Reported
	Naproxen	S	Oral	3 Mg Qd	Not Reported
	Naproxen	S	Unknown		Not Reported
	Naproxen	S			Not Reported
	Prednisone	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Prednisone	S	Oral	1.3 Mg, Bid	Not Reported
	Prednisone	S	Oral	1.3 Mg, Bid	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Prednisone	S	Oral	1.3 Mg Bid	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	50 Mg, Bid	Not Reported
	Prednisone	S	Unknown	50 Mg	Not Reported
	Immunoglobulin Iv	S	Intravenous (not otherwise specified)		Not Reported
	Immunoglobulin Iv	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Immunoglobulin Iv	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Immunoglobulin Iv	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Qw	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Qow	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2, Qow	Not Reported
	Methotrexate	S			Not Reported

Methotrexate	S			Not Reported
Triamcinolone Acetonide	S	Intra-articular		Sanofi
Triamcinolone Acetonide	S	Unknown	Unk	Sanofi
Triamcinolone Acetonide	S	Unknown		Sanofi
Triamcinolone Acetonide	S	Unknown	Unk	Sanofi
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qw	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Bid	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Adalimumab	S	Unknown	Unk	Not Reported
Anakinra	S	Subcutaneous	50 Mg, Qw	Not Reported
Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
Anakinra	S	Unknown	50 Mg	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	12.5 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	25 Mg, Qow	Not Reported
Enbrel	S	Subcutaneous	25 Mg	Not Reported
Enbrel	S	Subcutaneous	25 Mg, Qw	Not Reported
Etanercept	S	Subcutaneous	12.5 Mg	Not Reported
Etanercept	S	Subcutaneous	25 Mg, Qow	Not Reported
Humira	S	Unknown		Not Reported
Humira	S			Not Reported
Humira	S	Subcutaneous	Form: Solution	Not Reported
Humira	S			Not Reported

	Infliximab	S	Intravenous (not otherwise specified)	Unk Unk, Q6w	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
	Infliximab	S	Unknown	5 Mg	Not Reported
	Infliximab	S	Unknown	3 Mg/Kg, Q6w	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S		250 Mg, Qm	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Q2m	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous drip	250 Mg, Qm	Not Reported
	Orencia	S			Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
	Triamcinolone Hexacetonide	S	Other		Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unk	Not Reported
	Folic Acid	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600446	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA076650			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive;	Hydroxychloroquine Sulfate			S		5 Mg/Kg, Qd		Sanofi

Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Methotrexate	S	Subcutaneous	15 Mg/M2, Qw	Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Prednisone	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Triamcinolone Acetonide	S	Unknown		Sanofi
	Adalimumab	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg	Not Reported
	Enbrel	S	Subcutaneous	25 Mg	Not Reported
	Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Infliximab	S	Unknown	5 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600447	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA076649			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human	Hydroxychloroquine Sulfate			S	Oral	5.0 Mg/Kg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S	Unknown			Sanofi
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S		5 Mg, Bid		Not Reported

Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported
	Adalimumab	S	Subcutaneous			Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Qw		Not Reported
	Enbrel	S		12.5 Mg, Qw		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg, Qw		Not Reported
	Infliximab	S		5 Mg		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17600654	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10154		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Infliximab			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution		Not Reported
	Cimzia			S	Unknown	Unknown		Not Reported
	Cosentyx			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Otezla			S	Oral	Unknown		Not Reported
	Otezla			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported

	Rituximab	S	Unknown	Unknown		Not Reported
	Simponi	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Penicillin	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17601616	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10007		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Etanercept			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Biaxin			S	Unknown	Unknown		Not Reported
	Celebrex			S	Unknown	Unknown		Not Reported
	Cephalexin Monohydrate			S	Unknown	Unknown		Not Reported
	Ciprofloxacin			S	Unknown	Unknown		Not Reported
	Clindamycin Phosphate			S	Unknown	Unknown		Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Enalapril			S	Unknown	Unknown		Not Reported
	Fosamax			S	Unknown	Unknown		Not Reported
	Hctz			S	Unknown	Unknown		Not Reported
	Hydralazine Hydrochloride			S	Unknown	Unknown		Not Reported
	Levaquin			S	Unknown	Unknown		Not Reported
	Losartan			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Metoprolol Tartrate			S	Unknown	Unknown		Not Reported
	Moxifloxacin Hydrochloride			S	Unknown	Unknown		Not Reported
	Pantoprazole Magnesium			S	Unknown	Unknown		Not Reported
	Pariet			S	Unknown	Unknown		Not Reported

Penicillin G [Benzylpenicillin]	S	Unknown	Unknown		Not Reported
Hydroxychloroquine	S	Unknown	Unknown		Not Reported
Cipro [Ciprofloxacin]	C	Unknown	Unknown		Not Reported
Esomeprazole	C	Unknown	Unknown		Not Reported
Gold	C	Unknown	Unknown		Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unknown		Not Reported
Iron Sucrose	C	Unknown	Unknown		Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17602693	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026610		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17605425	DIRECT	Y	DE, LT			87 YR	Male	USA

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

Coronavirus Test Positive; Cough; Electrocardiogram Qt Prolonged; Urine Odour Abnormal	Hydroxychloroquine	S	Not Reported
	Azithromycin 250 Mg Tablet	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	13350239	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP008095		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission; Product Dose Omission	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Apo-Prednisone			S	Unknown	2 Df, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Prednisone			S	Unknown	2 Df, Q.O.D.		Not Reported
	Folic Acid			S	Unknown	Unk, Q.Wk.		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Actemra			S	Subcutaneous	162 Mg, Q.Wk.		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	281 Mg, 1 Every 4 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	281 Mg		Not Reported
	Arava			S	Oral	20 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Unknown	25 Mg, Q.Wk.		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	15711597	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-113698		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Limb Discomfort; Off Label Use; Rash; Rheumatoid Arthritis; Urticaria	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Q2wk		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Q2wk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

	Prednisone		C	Unknown	Unk	Not Reported
	Tofacitinib Citrate		C	Unknown	Unk	Not Reported
	Viread		C	Unknown	Unk	Not Reported
	Methotrexate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16079854	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05830		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Off Label Use; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Duration 705		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Ciclosporin			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown. Solution	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Gold	S	Unknown	Unknown	Not Reported
Gold	S	Intramuscular	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S			Not Reported
Apo-Azathioprine	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Leflunomide	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Anakinra	S	Unknown	Unknown	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16079890	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06218		9 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective;	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported

General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Dispensing Error; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Unknown		Not Reported
	Abatacept	S	Unknown	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Orencia	S			Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Tocilizumab	S	Unknown	Unknown	Not Reported
	Tocilizumab	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16085223	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06099		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported

Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unknown, Solution	Not Reported
	Humira	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Other	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16094586	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA057581		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Arthropathy; Contraindicated Product	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported

Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Methotrexate	S	Unknown	Unk Unk, Qw	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk (Solution Subcutaneous)	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Bid	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Naprosyn	C	Unknown	Unk	Not Reported
	Erythromycin	C	Unknown	Unk	Not Reported
	Morphine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16358401	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-049379		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Biaxin			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Clindamycin			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enalapril			S	Unknown	Unk		Not Reported

Steatosis; Hypertension; Loss Of Employment; Malaise; Nausea; Off Label Use; Product Use Issue; Rash; Therapeutic Product Effect Decreased	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hctz	S	Unknown	Unk	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
	Keflex [Cefalexin]	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Losartan	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.	S	Unknown	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported
	Cephalexin Monohydrate	S	Unknown		Not Reported
	Gliclazide	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Isoniazid	S	Unknown		Not Reported
	Lopressor	S	Unknown		Not Reported
	Losartan Potassium	S	Unknown		Not Reported
	Tecta	S	Unknown		Not Reported
	Xeljanz	S	Oral	50 Milligram, Bid	Not Reported
	Enalapril Maleate	S	Unknown		Not Reported
	Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk	Not Reported
	Cephalexin [Cefalexin]	S	Unknown	Unk	Not Reported

Clindamycin Phosphate	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Milligram	Not Reported
Venofer	C	Unknown		Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Iron Sucrose	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
Atenolol	C	Unknown		Not Reported
Colchicine	C	Unknown		Not Reported
Coversyl [Perindopril Erbumine]	C	Unknown		Not Reported
Leucovorin [Folinic Acid]	C	Unknown		Not Reported
Levothyroxine Sodium	C	Unknown		Not Reported
Ranitidine	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16443477	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018-03342		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use;	Etanercept			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown		Not Reported
	Cimzia			S	Unknown	Unknown		Not Reported

Pain; Product Use In Unapproved Indication; Rash; Rheumatoid Arthritis; Sleep Disorder	Cimzia	S	Subcutaneous	Unknown Solution	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Humira	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Leflunomide	S			Not Reported
	Minocycline Hydrochloride	S	Unknown	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Unknown Solution	Not Reported
	Myochrysine	S	Subcutaneous	Unknown	Not Reported
	Myochrysine	S	Parenteral	Unknown Solution Intramuscular	Not Reported
	Myochrysine	S	Unknown	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Unknown	Not Reported
	Orencia	S	Unknown		Not Reported
	Otezla	S	Oral	Unknown	Not Reported
	Otezla	S	Unknown	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Sirukumab	S	Unknown	Unknown	Not Reported
	Sirukumab	S			Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unknown	Not Reported
	Stelara	S	Subcutaneous	Unknown Solution	Not Reported
	Stelara	S	Unknown	Unknown	Not Reported
	Tocilizumab	S	Unknown	Unknown	Not Reported
	Tofacitinib Citrate	S	Oral		Not Reported
	Ustekinumab	S	Unknown	Unknown	Not Reported
	Ustekinumab	S	Subcutaneous	Unknown	Not Reported

Xeljanz	S	Oral		Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Intravenous drip	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Unknown	Not Reported
Minocycline	S	Unknown	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown Solution	Not Reported
Simponi	S	Unknown	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown	Not Reported
Salazopyrin	S	Unknown	Unknown	Not Reported
Apremilast	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Minocin	S	Unknown	Unknown	Not Reported
Methotrexate	C	Unknown	Unknown	Not Reported
Methotrexate	C	Unknown		Not Reported
Prednisone	C	Unknown	Unknown	Not Reported
Orencia	C	Unknown	Unknown	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Unknown Powder For Solution	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Unknown	Not Reported
Orencia	C	Unknown	Unknown	Not Reported
Orencia	C	Unknown		Not Reported
Plaquenil	C	Unknown	Unknown	Not Reported
Salazopyrin	C	Unknown	Unknown	Not Reported
Rheumatrex	C	Unknown	Unknown	Not Reported
Abatacept	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16788654	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA249407		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Diclofenac			S	Ophthalmic	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Mg		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Q12h		Not Reported
	Topicort			S	Cutaneous	Unk		Sanofi
	Prednisone			S	Oral	Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Sanofi
	Arava			S	Oral	Unk		Sanofi
	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown	10 Mg		Not Reported
	Cortisone Acetate			S	Topical	25 Mg		Not Reported
	Desoximetasone			S	Oral	Unk		Sanofi
	Folic Acid			S	Unknown	5 Mg		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Sanofi
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

		otherwise specified)		
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe	Not Reported
Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Mg, Qd	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfathalidine	S	Oral	500 Mg	Not Reported
Sulfathalidine	S	Oral	1000 Mg, Q12h	Not Reported
Tofacitinib	S	Unknown	5 Mg, Q12h	Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, Q12h	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16877937	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-28737		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported

Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral	Unknown	Not Reported
	Ciclosporin	S	Oral	Unknown	Not Reported
	Ciclosporin	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Imuran	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Certolizumab Pegol	S	Unknown		Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Lyrica	S	Unknown	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Simponi	S	Unknown	Unknown, Solution	Not Reported

				Subcutaneous		
	Sodium Aurothiomalate	S	Unknown	Unknown		Not Reported
	Tocilizumab	S	Unknown			Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Unknown		Not Reported
	Xeljanz	S	Oral			Not Reported
	Piroxicam	C	Unknown	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	16906473	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201909001003			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk,		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17194720	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-201912002914			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthma; Asthma; Chest Discomfort; Chest X-Ray Abnormal; Fall; Glaucoma; Joint Swelling; Macular Degeneration; Musculoskeletal Disorder; Musculoskeletal Pain; Nausea; Pneumonia; Pyrexia; Respiratory Tract Infection Bacterial; Retinal Toxicity; Rib Fracture; Therapeutic Response	Hydroxychloroquine			S	Unknown	Unk, Plaquenil		Concordia
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk, Qd (1in 1d)		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	(1 In 2 Wk)		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	Unk, Weekly, (1 In 1 Wk),		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	Unk,Solution For Infusion In Pre-Filled Syringe		Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous	(1 In 1 Wk)		Not Reported
	Humira			S	Subcutaneous	Citrate Free		Not Reported

Shortened; Wheelchair User; White Blood Cell Count Increased	Iron		C	Unknown	Unk	Not Reported
	Folic		C	Unknown	Unk	Not Reported
	Eliquis		C		Unk	Not Reported
	Prilosec		C		Unk	Not Reported
	Zantac		C		Unk	Not Reported
	Losartan		C		Unk	Not Reported
	Flexeril		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17287199	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2020-00706			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported

Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)		Not Reported
	Intravenous Immunoglobulin	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Naproxen Sodium	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Naproxen	S			Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported

Gamastan	S	Intramuscular		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)		Not Reported
Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)		Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Naproxen	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Triamcinolone	S	Unknown	Unknown	Not Reported
Triamcinolone Acetonide	S	Intra-arterial	Unknown Suspension Intra Articular	Not Reported
Triamcinolone Acetonide	S	Intra-arterial	Unknown	Not Reported
Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported
Triamcinolone Acetonide	S			Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported
Folic Acid	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17433133	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0824		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Arthralgia; Arthropathy; Condition Aggravated; Deformity; Diarrhoea; Disease Progression;	Kineret			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Drug Ineffective; Drug Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Warfarin	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Warfarin	S	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17521215	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1193557		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Paradoxical Drug Reaction; Sleep Disorder; Varicella Zoster Virus Infection	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			S	Unknown	40 Milligram Daily;		Actavis
	Prednisone			S	Unknown	Tapered Down From 40 Mg/Day To 20 Mg/Day Over The Previous 4 Weeks		Actavis
	Azathioprine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17557563	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318947			Female	CAN

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

Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Simponi	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17557583	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318935		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17597116	EXPEDITED (15-DAY)		HO, OT	JP-ADVANZ PHARMA-GSH201903-000649			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Conjunctivitis Bacterial; Gnathoschisis; Herpes Zoster; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Valganciclovir Hydrochloride			S	Oral	1800 Mg, Qd		Not Reported
	Prograf			S	Oral	3 Mg, Qd		Not Reported
	Prograf			S	Oral	2 Mg, Qd		Not Reported
	Prograf			S	Oral	1.5 Mg, Qd		Not Reported
	Prograf			S	Oral	2 Mg, Qd		Not Reported
	Prednisolone			S	Oral	25 Mg, Qd		Not Reported
	Prednisolone			S	Oral	40 Mg, Qd		Not Reported
	Prednisolone			S	Oral	30 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd		Not Reported
	Prednisolone			S	Oral	17.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported
	Prednisolone			S	Oral	12.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Prednisolone			S	Oral	9 Mg, Qd		Not Reported
	Prednisolone			S	Oral	8 Mg, Qd		Not Reported
	Prednisolone			S	Oral	7 Mg, Qd		Not Reported
	Prednisolone			S	Oral	6 Mg, Qd		Not Reported
	Prednisolone			S	Oral	5 Mg, Qd		Not Reported
	Bayaspirin			C		Unk		Not Reported
	Rabeprazole Sodium			C		Unk		Not Reported
	Rabeprazole Sodium			C				Not Reported
	Halizon			C		Unk		Not Reported
	Pitavastatin Calcium			C		Unk		Not Reported
	Pitavastatin Calcium			C				Not Reported

Alendronate	C	Unk	Not Reported
Alendronate	C		Not Reported
Daiphen	C	Unk	Not Reported
Daiphen	C		Not Reported
Nitrazepam	C	Unk	Not Reported
Evoxac	C	Unk	Not Reported
Magnesium Oxide	C	Unk	Not Reported
Equa	C	Unk	Not Reported
Januvia	C	Unk	Not Reported
Humulin R	C	Unk	Not Reported
Aiphagan	C	Unk	Not Reported
Lumigan	C	Unk	Not Reported
Timoleate	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17601685	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002044			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Breast Cancer Metastatic; Burning Sensation; Constipation; Dementia Alzheimer'S Type; Expired Product Administered; Gait Disturbance; Intentional Product Misuse; Malaise; Off Label Use; Paronychia; Skin Plaque; Systemic Lupus Erythematosus; Toe Amputation	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Bid (One In Morning And One In Evening, Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	3 Dosage Form (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Amoxicillin Trihydrate/Potassium Clavulanate			S	Unknown	Unk		Not Reported
	Amoxicillin Trihydrate/Potassium Clavulanate			S				Not Reported
	Amoxicillin Trihydrate/Potassium Clavulanate			S				Not Reported
	Lercan			C		10 Mg		Not Reported
	Quinine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17601958	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571285			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17602357	NON-EXPEDITED			US-APPCO PHARMA LLC-2082131		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma
	Synthroid			C	Unknown			Not Reported
	Januvia			C	Unknown			Not Reported
	Olmesartan Medoxomil And Hydrochlorothiazide			C	Unknown			Not Reported
	Troujeo			C	Unknown			Not Reported
	Ezetimibe			C	Unknown			Not Reported
	Vitamin B Complex			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17602740	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003001986			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blindness	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17603176	EXPEDITED (15-DAY)		HO	NVSC2020CA086171		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17603214	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025877			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	400 Milligram		Not Reported
Methotrexate	S	Unknown	25 Milligram, Qwk		Not Reported
Rituximab	S	Intravenous drip	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605057	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA076608		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Hydroxychloroquine Sulfate			S	Oral	5 Mg, Qd		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S	Unknown			Sanofi
	Actemra			S	Intravenous (not otherwise specified)	280 Mg		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605175	EXPEDITED (15-DAY)		OT	CA-SA-2019SA247463			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Depression; Drug	Plaquenil			S		Unk		Sanofi

Ineffective; Drug Intolerance; Hypersensitivity; Myelopathy; Neuropathy Peripheral	Arava	S		Unk Unk, Unk	Sanofi
	Buprenorphine	C		10 Ug, Qd	Not Reported
	Xarelto	C		15 Mg, Qd	Not Reported
	Bisoprolol	C		12.5 Mg, Qd	Not Reported
	Lasix [Furosemide Sodium]	C		20 Mg (20mg Od/Q2days Depending On Need)	Not Reported
	Lasix [Furosemide Sodium]	C		Unk	Not Reported
	Vitamin D [Vitamin D Nos]	C		Unk	Not Reported
	Vitamin B12 Nos	C		Unk	Not Reported
	Vitamin B6	C		Unk	Not Reported
	Fish Oil	C		Unk Unk, Unk	Not Reported
	Calcium	C		Unk Unk, Unk	Not Reported
	Magnesium	C		Unk Unk, Unk	Not Reported
	Ramipril	C		12.5 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Prednisone	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605318	EXPEDITED (15-DAY)		OT	AU-SA-2020SA072232		34 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Adrenal Haemorrhage; Atrial Septal Defect; Cerebral Infarction; Deep Vein Thrombosis; Myocardial Hypoperfusion; Myocarditis; Pulmonary Embolism; Pulmonary Infarction; Thrombotic Microangiopathy; Transient Ischaemic Attack	Enoxaparin Sodium			S		200 Mg		Sanofi
	Acetylsalicylic Acid			S		100 Mg		Not Reported
	Hydroxychloroquine			S		200 Mg		Sanofi
	Cyclophosphamide Monohydrate			C	Intravenous (not otherwise specified)	1.5 G		Not Reported
	Heparin Sodium			C				Not Reported
	Rituximab			C		1 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605363	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-09913		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi	S	Subcutaneous	Unknown		Not Reported
	Xeljanz	S	Oral			Not Reported
	Xeljanz	S	Oral			Not Reported
	Xeljanz	S	Unknown			Not Reported
	Acetaminophen	C	Unknown			Not Reported
	Cetirizine Hydrochloride	C	Unknown			Not Reported
	Cortisone	C	Unknown	Unknown		Not Reported
	Desoximetasone	C	Unknown	Unknown		Not Reported
	Gabapentin	C	Unknown			Not Reported
	Paracetamol	C	Unknown	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605416	DIRECT	Y	DE			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cardiac Arrest; Corona Virus Infection; Pneumonia; Renal Failure; Ventricular Tachycardia	Hydroxychloroquine			S	Oral		5 DAY	Not Reported
	Acetaminophen			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cisatricurium			C				Not Reported
	Doxycycline			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Pantoprazole			C				Not Reported
	Midazolam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605439	DIRECT	Y	LT			85 YR	Male	USA

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

Drug Interaction; Tachycardia	Plaquenil		S	Oral	Other Frequency:Load - Then 200mg;	Not Reported
	Azithromycin		C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605541	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP009047			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatotoxicity; Rash	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk. (Therapy Duration 365 Unit Unspecified)		Not Reported
	Infliximab			S	Unknown	5 Mg/Kg, One Every Eight Week		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk, Qd		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)	1 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605719	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10553		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown Powder For Solution For Infusion		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported

Hydroxychloroquine	S	Unknown	Unknown		Not Reported
Humira	S	Subcutaneous	Unknown		Not Reported
Enbrel	S	Unknown	Unknown		Not Reported
Anakinra	S	Unknown	Unknown		Not Reported
Actemra	S	Unknown	Unknown		Not Reported
Desoximetasone	C	Unknown	Unknown		Not Reported
Methotrexate	C	Oral			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605780	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200331857		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Metformin Hydrochloride			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Altace			C				Not Reported
	Asa			C				Not Reported
	Ergocalciferol			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C	Oral			Not Reported
	Rosuvastatin Calcium			C				Not Reported
	D-Alpha Tocopherol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17605804	EXPEDITED (15-DAY)		OT	US-APPCO PHARMA LLC-2082143			Female	USA

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

Adverse Drug Reaction	Hydroxychloroquine Sulfate	S	Unknown		Appco Pharma

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17606206	EXPEDITED (15-DAY)		OT	IT-TEVA-2020-IT-1212925		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Teva
	Dabigatran Etexilate			S	Oral	300 Mg		Not Reported
	Daparox			S	Unknown			Not Reported
	Lamictal			S	Unknown			Not Reported
	Valium			S	Unknown			Not Reported
	Sotalol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17606630	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025455		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17606828	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA085981		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Oral	Unk Unk, Bid		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unknown		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	5 Mg, Bid		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone Acetate			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	50 Mg, Bid		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	2 Df, Qd		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Folic Acid			C	Subcutaneous	Unk		Not Reported
	Insulin			C	Oral	Unk		Not Reported
	Metformin			C	Unknown	2 Df, Bid		Not Reported

	Plaquenil			C	Unknown	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17608508	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-015824		54 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Headache; Palpitations	Risedronate			S	Oral	35 Milligram, Total		Aurobindo
	Plaquenil			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Cortancyl			S	Oral	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Izalgi			C	Unknown	Unk		Not Reported
	Levothyrox			C	Unknown	Unk		Not Reported
	Diffu K			C	Unknown	Unk		Not Reported
	Atorvastatine			C	Unknown	Unk		Not Reported
	Clopidogrel Hydrochloride			C	Unknown	Unk		Not Reported
	Procoralan			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	17611030	DIRECT	Y	DE, DS, LT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Corona Virus Infection; Electrocardiogram Qt Prolonged; Pneumonia Viral	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15620857	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556897-00		63 YR	Female	CAN

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

Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15626375	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555933-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Meloxicam	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Mobicox	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Sulfasalazine	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15668473	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570151-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Off Label Use; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change; Toe Amputation	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C				Not Reported
	Synthroid			C				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15712088	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588120-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Remicade			S	Intravenous drip	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15712568	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587985-00		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported

Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Toradol	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15713594	EXPEDITED (15-DAY)		HO	CA-ABBVIE-18K-028-2583819-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Desoximetasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15738111	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594168-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Meloxicam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	15741654	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594158-00		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

	Apo-Leflunomide	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	16156007	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2728799-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Septra			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	16798598	EXPEDITED (15-DAY)		OT	CA-SA-2019SA250726		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug	Desoximetasone			S	Oral	Unk		Sanofi
	Desoximetasone			S	Oral	Unk		Sanofi
	Cortisone Acetate			S	Oral			Not Reported
	Diclofenac Sodium			S				Not Reported
	Topicort			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Prednisone			S				Not Reported

Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Arava	S	Oral		Sanofi
	Cetirizine Hydrochloride	S			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S			Not Reported
	Folic Acid	S		1 Mg	Not Reported
	Alendronate Sodium	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S		400 Mg, Qd	Sanofi
	Methotrexate	S	Oral	Unk	Not Reported
	Plaquenil	S		400 Mg, Qd	Sanofi
	Prednisone	S			Not Reported
	Pseudoephedrine Hydrochloride	S		Unk	Sanofi
	Sarilumab	S			Sanofi
	Sulfasalazine	S	Subcutaneous	1 G, Bid	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Desoximetasone	S			Sanofi
	Actemra	S			Not Reported
	Cortisone Acetate	S		Unk	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Reactine [Cetirizine Hydrochloride]	S		10 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S			Not Reported

Leflunomide	C		Not Reported
Atasol [Paracetamol]	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	16805660	EXPEDITED (15-DAY)		DE	CA-TEVA-2019-CA-1108101		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort	Alendronate Sodium			S	Unknown			Actavis
	Atorvastatin Calcium			S	Unknown			Teva
	Ipratropium Bromide/Salbutamol Sulfate			S	Unknown			Teva
	Metformin			S	Unknown	1000 Milligram Daily;		Not Reported
	Omeprazole Magnesium			S	Oral			Teva
	Furosemide			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Flovent			S	Unknown			Not Reported
	Lasix			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17159637	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1122784			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension;	Spasmolyt			S	Unknown	30 Milligram, Qd(30 Mg, Qd; Number Of Separate Dosages: 1 Number Of Units In The Interval: 1)		Mylan
	Spasmolyt			S	Unknown	1 Dosage Form, Qd (1 Df, Qd; 1 Number Of Units In		Mylan

Therapeutic Product Effect Incomplete; Visual Impairment				The Interval: 1)	
	Pregabalin	S	Unknown	1 Df, Tid (1 – 1 - 1)	Not Reported
	Pregabalin	S	Unknown	300 Milligram, Qd (100 Milligram, Tid)	Not Reported
	Omeprazole	S	Oral	2 Dosage Form, Qd(1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12)	Not Reported
	Ramipril	S	Oral	2 Dosage Form, Qd(1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12)	Not Reported
	Ambrisentan	S	Unknown	1 Dosage Form, Qd	Not Reported
	Ambrisentan	S	Unknown	30 Milligram, Qd	Not Reported
	Sildenafil	S	Unknown	60 Milligram, Qd (60 Milligram, Daily Dose)	Not Reported
	Quensyl	S	Unknown	1 Df, Bid (1 – 0 - 1)	Mylan
	Quensyl	S	Unknown	2 Dosage Form, Qd (1 Df, Bid (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The	Mylan
	Eliquis	S	Unknown	1 Df, Bid (1 – 0 - 1)	Mylan
	Eliquis	S	Unknown	5 Milligram, Qd (2.5 Milligram, Bid)	Mylan
	Roactemra	S	Subcutaneous	162 Milligram, Qw (162 Milligram, Qwk)	Mylan
	Roactemra	S	Subcutaneous	162 Milligram, Qw	Mylan
	Volibris	S	Oral	30 Milligram, Qd	Mylan
	Volibris	S	Oral	1 Dosage Form, Qd	Mylan
	Lyrica	S	Unknown	300 Milligram, Qd(100 Milligram, Tid)	Mylan
	Apixaban	S		5 Milligram, Qd(2.5 Milligram, Bid)	Mylan
	Apixaban	S		5 Milligram, Qd(2.5	Mylan

Milligram, Bid)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17430893	NON-EXPEDITED			NVSC2020US036804			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
B-Lymphocyte Abnormalities; Foetal Exposure During Pregnancy	Rituximab			S	Transplacental	Maternal Dose: 500 Mg/M2		Not Reported
	Azathioprine			S	Transplacental	Maternal Dose: 100 Mg, Bid		Not Reported
	Prednisone			S	Transplacental	Maternal Dose: 5 Mg, Qd		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 20 Mg, Qd		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 1 Mg/Kg, Qd		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 10 Mg, Qd		Novartis
	Hydroxychloroquine			S	Transplacental	Maternal Dose: Unknown		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 3micrograms/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 5 Micrograms/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 1.5 Micrograms/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 2 Microgram/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 1microgram/Kg		Not Reported
	Dexamethasone			S	Transplacental	Maternal Dose: 10mg		Not Reported
	Dexamethasone			S	Transplacental	Maternal Dose: 40 Mg		Not Reported
	Belimumab			S	Transplacental	Maternal Dose: Unk, Qmo		Not Reported
	Iviglob-Ex			S	Transplacental	Maternal Dose: 500 Mg/Kg		Not Reported
	Iviglob-Ex			S	Transplacental	Maternal Dose: 1000 Mg/Kg		Not Reported

	Iviglob-Ex	S	Transplacental	Maternal Dose: 400 Mg/Kg	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 200 Mg/Kg	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg, Tiw	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg, Q2w	Not Reported
	Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg, Tiw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17432480	NON-EXPEDITED			NVSC2020US036797		29 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Rituximab			S	Intravenous (not otherwise specified)	500 Mg/M2		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Novartis
	Prednisone			S	Unknown	20 Mg, Qd		Novartis
	Prednisone			S	Oral	1 Mg/Kg Qd		Novartis
	Prednisone			S	Unknown	10 Mg Qd		Novartis
	Azathioprine			S	Unknown	100 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Romiplostim			S	Subcutaneous	3 Micrograms/Kg		Not Reported
	Romiplostim			S	Unknown	5 Micrograms/Kg, Qw		Not Reported
	Romiplostim			S	Unknown	1.5 Micrograms/Kg, Qw		Not Reported
	Romiplostim			S	Unknown	2 Micrograms/Kg		Not Reported
	Romiplostim			S	Unknown	1 Microgram		Not Reported
	Belimumab			S	Unknown	Unk Unk, Qmo		Not Reported
	Dexamethasone			S	Unknown	10 Mg		Not Reported
	Dexamethasone			S	Oral	40 Mg		Not Reported
	Iviglob-Ex			S	Unknown	500 Mg/Kg		Not Reported
	Iviglob-Ex			S	Unknown	1000 Mg/Kg		Not Reported

	Iviglob-Ex		S	Unknown	400 Mg/Kg	Not Reported
	Iviglob-Ex		S	Unknown	200 Mg/Kg	Not Reported
	Iviglob-Ex		S	Unknown	500 Mg/Kg, Tiw	Not Reported
	Iviglob-Ex		S	Unknown	500 Mg/Kg, Q2w	Not Reported
	Iviglob-Ex		S	Unknown	500 Mg/Kg, Tiw	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17570316	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008939		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Arthrotec			C	Oral	Unk		Not Reported

	Arthrotec	C	Unknown	Unk		Not Reported
	Azathioprine	C	Unknown	Unk		Not Reported
	Ergocalciferol	C	Unknown	Unk		Not Reported
	Gold	C	Unknown	Unk		Not Reported
	Imuran /00001501/	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17571510	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008899			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17586904	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024281		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased;	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	680 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	360 Milligram, Qmo		Not Reported
	Alendronic Acid			S	Unknown	70 Milligram, Qwk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram, Bid	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608636	EXPEDITED (15-DAY)		OT	FR-FERRINGPH-2020FE01903		42 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Menopur			S	Subcutaneous			Ferring
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608696	EXPEDITED (15-DAY)		OT	IT-BAXTER-2020BAX006523		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Diretif 10 Mg/Ml Soluzione Iniettabile			S	Unknown			Claris
	Dabigatran Etexilate			S	Oral			Not Reported
	Daparox			S	Unknown			Not Reported

	Lamictal	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Valium	S	Unknown	Not Reported
	Sotalol	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608746	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001933			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anterior Chamber Disorder; Blindness; Epstein-Barr Virus Infection; Eye Pain; Eye Pain; Intraocular Pressure Increased; Necrotising Retinitis; Ocular Hyperaemia; Retinal Detachment; Scleral Disorder; Uveitis; Varicella Zoster Virus Infection; Vision Blurred; Vitreous Floaters; Vitritis	Hydroxychloroquine			S	Unknown	200 Mg, Qd, Tablet		Concordia
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Cellcept			S	Unknown	1000 Mg, Bid		Not Reported
	Valacyclovir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608765	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1216776			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Atorvastatin			S				Teva
	Methotrexate			S				Barr
	Plaquenil			S		400 Milligram Daily;		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Alprazolam			C				Not Reported
	Folic Acid			C				Not Reported
	Naprosyn			C		1000 Milligram Daily;		Not Reported
	Pantoloc			C				Not Reported

	Prednisone	C	5 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17608937	EXPEDITED (15-DAY)		DS, HO, OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-000912			Unknown	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Congestive Cardiomyopathy; Dyspnoea; Left Ventricular Dysfunction	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Qd		Ipca
	Fexofenadine			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Novo Nordisk Pharms Novofem			C	Unknown	Unk		Not Reported
	Amitriptyline			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported
	Hyoscine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17609185	EXPEDITED (15-DAY)		HO, LT, OT	CA-ADVANZ PHARMA-GSH201702-001124			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Condition Aggravated; Diarrhoea;	Hydroxychloroquine			S	Oral	5 Mg/Kg, Qd		Concordia
	Hydroxychloroquine			S		Unk		Concordia
	Adalimumab			S	Unknown	Unknown		Not Reported
	Abatacept			S	Intravenous (not otherwise specified)	250 Mg, Monthly		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported

Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Weekly	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Anakinra	S	Subcutaneous	50 Unk	Not Reported
	Etanercept	S	Subcutaneous	25 Mg, Weekly	Not Reported
	Etanercept	S	Subcutaneous	12.5 Mg, Weekly	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2 Qow	Not Reported
	Methotrexate	S	Unknown	Unk, Weekly	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Prednisone	S	Unknown	1.3 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Sulfasalazine	S			Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Weekly	Not Reported
	Tocilizumab	S	Unknown	250 Mg, Qd	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg Qcy (Every 2 Weel)	Not Reported

	Isoniazid;Rifampicin	S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Folic Acid	C				Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17609386	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA086791		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Meperidine Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Novartis
	Bisoprolol			S	Unknown	Unk		Novartis
	Levofloxacin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Qw		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Mg, Qd		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin Estolate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Mg		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	5 Mg		Not Reported
	Norfloxacin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17609994	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-177659		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Pneumonia	Methotrexate			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17610209	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2020050661		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Lamotrigine			S	Unknown	Unk		Glaxosmithkline
	Furosemide			S	Unknown	Unk		Glaxosmithkline
	Daparox			S	Unknown	Unk		Glaxosmithkline
	Valium			S	Unknown	Unk		Glaxosmithkline
	Plaquenil			S	Unknown	Unk		Not Reported
	Dabigatran Etexilate			S	Oral	300 Mg, Qd		Not Reported
	Sotalol			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17610630	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026351		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cefazolin			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, 1 Every 2 Weeks		Not Reported

Rheumatoid Arthritis; Unevaluable Event; Urticaria	Certolizumab Pegol		S	Subcutaneous	400 Milligram, 1 Every 2 Weeks	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	200 Milligram, 1 Every 2 Weeks	Not Reported
	Leflunomide		S	Oral	10 Milligram	Not Reported
	Methotrexate		S	Subcutaneous	25 Milligram, 1every One Week	Not Reported
	Methotrexate		S	Unknown	Unk	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Amlodipine		C	Unknown	Unk	Not Reported
	Arava		C	Unknown	Unk	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]		C	Unknown	Unk	Not Reported
	Naproxen		C	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported
	Tofacitinib Citrate		C	Unknown	Unk	Not Reported
	Viread		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611049	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-09980			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown	Unknown		Not Reported

Stiffness; Neck Pain; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Actemra	S	Unknown	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	Unknown		Not Reported
	Arava	S	Unknown	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous			Not Reported
	Certolizumab Pegol	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	Unknown		Not Reported
	Methotrexate	S	Subcutaneous			Not Reported
	Methylprednisolone	S	Unknown			Not Reported
	Orencia	S	Unknown	Unknown		Not Reported
	Plaquenil	S	Unknown	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown		Not Reported
	Xeljanz	S	Unknown	Unknown		Not Reported
	Naproxen	C	Unknown	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown		Not Reported
	Rituxan	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611066	DIRECT	Y	DS, OT			76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Immunosuppressant Drug Level Increased	Plaquenil			S				Not Reported
	Azithromycin 500 Mg Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611141	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10625			Female	CAN

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

Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Infliximab	S	Unknown	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Anakinra	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Sulfasalazine	S	Oral	Unknown	Not Reported
	Prednisone	C	Unknown		Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Methotrexate	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611326	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160600430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611609	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10259			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Sodium Aurothiomalate		S	Intramuscular	Unknown	Not Reported
	Sulfasalazine		S	Oral		Not Reported
	Sulfasalazine		S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17611785	EXPEDITED (15-DAY)		OT	IT-VALIDUS PHARMACEUTICALS LLC-IT-2020VAL000236			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S	Unknown	Unk		Validus
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown	Unk		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported
	Sotalol Hydrochloride			S	Unknown	Unk		Not Reported
	Dabigatran			S	Oral	Unk		Not Reported
	Daparox /00830803/			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17614765	DIRECT	Y	DE, LT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Corona Virus Infection; Cytokine Storm; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	Other Dose:400-200 Mg;		Not Reported
	Haldol			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Cefepime			C				Not Reported
	Chlorhexidine			C				Not Reported
	Cistaracurijm			C				Not Reported
	Docusate Sodium			C				Not Reported
	Exoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Versed			C				Not Reported
	Propofol Continuous Infusion			C				Not Reported
	Pantoprazole			C				Not Reported

Sennosides	C	Not Reported
Sertraline	C	Not Reported
Darunavir/Cobistat	C	Not Reported
Apixaban	C	Not Reported
Aspirin	C	Not Reported
Donepezil	C	Not Reported
Ketoconazole 2% Shampoo	C	Not Reported
Nitroglycerin Sl	C	Not Reported
Sertrraline	C	Not Reported
Sevelamer	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	11626328	EXPEDITED (15-DAY)		DS, LT, OT	CA-UCBSA-2015032127		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus;	Cimzia			S	Subcutaneous	Dosage Form: Solution		Not Reported
	Cimzia			S				Not Reported
	Cetirizine Hydrochloride			S		10 Mg, Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride			S	Oral	10 Milligram, Once Daily (Qd)		Ucb
	Cetirizine Hydrochloride			S	Oral	10 Milligram		Ucb
	Cetirizine Hydrochloride			S		Unk		Ucb
	Zyrtec-D			S		10 Mg, Unk		Not Reported
	Zyrtec-D			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		Controlled Release Tablets		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		25 Milligram, Ointment		Ucb
	Cirrus			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Dosage Form: Lyophilized Powder		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Folic Acid	S		5 Mg, Unk	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		1 Mg	Not Reported
	Folic Acid	S		500 Milligram	Not Reported
	Prednisone	S	Oral	Dosage Form: Unknown	Not Reported
	Prednisone	S		Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S		Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
	Sulfathalidine	S		Dosage Form: Unspecified	Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
	Humira	S	Subcutaneous	40 Mg (0.8 Ml)	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported

Methotrexate	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S		25 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	1000 Mg, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Sulfasalazine	S		Unk	Not Reported
Apo-Folic Acid	S		5 Mg, Unk	Not Reported
Apo-Hydroxyquine	S		Unk	Not Reported
Apo-Prednisone	S		1 Milligram	Not Reported
Apo-Prednisone	S		5 Milligram	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S		Unk	Not Reported
Pseudoephedrine Hydrochloride	S		Unk	Not Reported
Pseudoephedrine Hydrochloride	S		1 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S		25 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S		10 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S			Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported

Cortisone	S	Oral	25 Milligram	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Topicort	S	Cutaneous		Not Reported
Topicort	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Oral		Not Reported
Diclofenac Sodium	S		Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S		Unk Unk, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk Unk, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported
Xeljanz	S		Unk	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported
Xeljanz	S		Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Adalimumab	S		Unk	Not Reported
Paracetamol	S			Not Reported
Stelara	S			Not Reported
Actemra	S	Subcutaneous		Not Reported
Actemra	S			Not Reported
Cortisone	S	Oral		Not Reported
Cortisone Acetate	S	Oral	25 Milligram	Not Reported
Cortisone Acetate	S			Not Reported
Cortisone Acetate	S	Oral		Not Reported
Desoximetasone	S		Cutaneous Route	Not Reported
Desoximetasone	S	Oral		Not Reported
Diclofenac	S			Not Reported

Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Enbrel	S			Not Reported
Humira	S	Sunconjunctival	40 Milligram	Not Reported
Humira	S	Sunconjunctival	Unk Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Rituxan	S	Intravesical		Not Reported
Sarilumab	S			Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Subcutaneous		Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Subcutaneous		Not Reported
Topicort	S		Unk	Not Reported
Topicort	S	Cutaneous		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported
Golimumab	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Leflunomide	S			Not Reported
Methotrexate	S	Intra-arterial	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Salazopyrin	C		Unk	Not Reported
Atasol	C		Unk	Not Reported

	Tofacitinib Citrate	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	13058846	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015717		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Gold			S	Intramuscular			Not Reported
	Imuran /00001501/			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	13516082	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038066		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Off Label Use;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Methotrexate		S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Cellcept [Mycophenolate Mofetil]		S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		S	Unknown		Not Reported
	Imuran [Azathioprine]		S	Unknown	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz		C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	13669856	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA106082		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk, Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Xeljanz	C	Oral	5 Mg,Bid		Not Reported
	Prednisone	C	Unknown	5 Mg,Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	14217330	EXPEDITED (15-DAY)		OT	CA-ROCHE-2025441		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Remicade			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15509701	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016273080		61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Dysphagia; Gastrooesophageal Reflux	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer

Disease; Glaucoma; Pharyngeal Swelling	Xeljanz	S	Oral	5 Mg, 2x/Day	Pfizer
	Xeljanz	S	Oral	5 Mg, 2x/Day	Pfizer
	Plaquenil	S		200 Mg, 2x/Day	Not Reported
	Plaquenil	S		200 Mg, 2x/Day	Not Reported
	Atorvastatin	C		20 Mg, Unk	Not Reported
	Latanoprost	C		Unk [125mg/2.5ml]	Not Reported
	Stiolto Respimat	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15619727	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555831-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15620477	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2555079-00		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Aleve	S	Oral	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Methotrexate	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15627967	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2558814-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

			otherwise specified)	
	Etanercept	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15629653	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557267-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Imuran	C	Unknown	Not Reported
	Azathioprine	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15635108	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2556219-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Dysphonia; Gait Disturbance; Hospitalisation; Joint Swelling; Loss Of Consciousness; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Rheumatoid Arthritis; Secretion Discharge; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Apo-Warfarin			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported

	Prednisone		S	Unknown	Not Reported
	Amitriptyline		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15728721	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1969198-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

Methotrexate Sodium	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Apo-Leflunomide	S	Unknown			Not Reported
Apo-Hydroxyquine	S	Unknown	For 8 Years		Not Reported
Apo-Hydroxyquine	S	Unknown			Not Reported
Apo-Hydroxyquine	S	Unknown			Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown	For 8 Years		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown			Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Vitamin D3	C				Not Reported
Imuran	C				Not Reported
Gold	C				Not Reported
Arthrotec	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	15732982	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-1858378-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Naproxen	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	16337732	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-048239		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell	Ibuprofen			S	Oral	600 Milligram		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Apo Ibuprofen			S	Oral			Not Reported
	Apremilast			S	Unknown	60 Milligram		Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported

Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Methotrexate	S	Unknown	15 Milligram,1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	17.5 Milligram, 4 Every1week	Not Reported
	Methotrexate	S	Unknown	12 Milligram,4every1week	Not Reported
	Methotrexate	S	Unknown	10 Milligram,4every 1week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram,4every 1week	Not Reported
	Methotrexate	S	Unknown	70 Milligram,1every1week	Not Reported
	Otezla	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram,2every1day	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Endocervical		Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	25 Milligram,2every1week	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Motrin [Ibuprofen]	S	Oral	600 Milligram, Qd	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Gravol	C	Unknown		Not Reported
	Mogadon	C	Oral	5 Milligram	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown		Not Reported
	Colchicine	C	Oral		Not Reported
	Dexilant	C	Unknown		Not Reported
	Febuxostat	C	Unknown		Not Reported

Nitrazepam	C	Unknown	5 Milligram		Not Reported
Oxycodone	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Uloric	C	Unknown	80 Milligram,2every1day		Not Reported
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	16527868	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555951-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Solution-Dosage Form (Form Of Administration)		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported

	Xeljanz	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	16568503	EXPEDITED (15-DAY)		HO, OT	PHHY2019PL128630		35 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestasis Of Pregnancy; Erythema Nodosum; Maternal Exposure During Pregnancy; Normal Newborn	Erelzi			S	Intravenous (not otherwise specified)	50 Mg, Unk		Novartis
	Erelzi			S	Subcutaneous	50 Mg, Qw		Novartis
	Erelzi			S	Subcutaneous	50 Mg, Qw		Novartis
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Encorton			S	Unknown	10 Mg, Qd		Not Reported
	Encorton			S	Unknown	15 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Benepali			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	20 Mg, Qd		Not Reported
	Insulin			C	Unknown	Unk		Not Reported
	Metex			C	Subcutaneous	Unk (The Last Injection In Jan-2019)		Not Reported
	Metex			C	Subcutaneous	Unk (The Last Injection In Jan-2019)		Not Reported
	Folic			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	16820135	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201804-001105			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Dizziness; Fatigue; Hepatomegaly;	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

Malaise; Nausea; Pain In Extremity; Puncture Site Pain; Rash; Splenomegaly; Systemic Lupus Erythematosus; Vein Disorder; Vessel Puncture Site Bruise; Vessel Puncture Site Swelling	Cerezyme	S	Intravenous drip	Dose/Unit: 3200.00 Frequency: Q2	Not Reported
	Cerezyme	S	Intravenous (not otherwise specified)	3200 Mg, Qow	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17486761	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202002001091			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acantholysis; Blister; Dermatitis; Herpes Zoster; Inflammation; Macule; Pain; Pruritus; Skin Plaque; Varicella Zoster Virus Infection	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Prednisone			S	Unknown	40 Mg, Qd		Not Reported
	Prednisone			S	Unknown	20 Mg, Qd, Tapering Dose		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Recombinant Varicella Zoster Virus Glycoproteine E			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17566404	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318840		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive; Treatment	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported

Failure	Plaquenil /00072602/	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ergocalciferol	C			Not Reported
	Imuran /00001501/	C	Unknown		Not Reported
	Arthrotec	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17575062	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008919			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17609231	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002203			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17609364	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002205			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17609365	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002204			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17611781	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002279			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia

	Dabrafenib		S	Oral	150 Mg, Bid	Not Reported
	Trametinib		S		2 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17611782	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002280			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17611783	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002281			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17613937	EXPEDITED (15-DAY)		OT	CA-ROCHE-2572186			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Localised Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614080	EXPEDITED (15-DAY)		OT	AU-ADVANZ PHARMA-202003002074			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Disorder; Organ Transplant; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unk (For Over 30 Years)		Concordia
	Cellcept			S	Unknown	500 Mg, Tid (For 1.5 Years)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614116	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10342			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614240	EXPEDITED (15-DAY)		OT	CA-DRREDDYS-USA/CAN/20/0121425			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Stiffness; Joint Swelling; Pain; Rheumatoid Arthritis	Atorvastatin			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Trichlormethiazide			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614242	EXPEDITED (15-DAY)		HO	BR-ADVANZ PHARMA-202003002062			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Gait Disturbance; Herpes Zoster; Surgery	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Dosage Form, Qd		Concordia
	Aradois			C		50 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614339	EXPEDITED (15-DAY)		DS	CA-ROCHE-2572169		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Impairment; Mobility Decreased; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614467	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026601		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Orencia			S	Unknown			Bristol Myers Squibb
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported
	Asacol			S	Unknown	800 Milligram, Tid		Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gliclazide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Oral	650 Milligram		Not Reported
	Atacand Plus			C	Unknown			Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported

	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Ebastine	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616393	DIRECT					63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Substitution Issue; Vertigo	Hydroxychloroquine 200 Mg Tablets Zydus - Substituted For Plaquenil			S	Oral	Quantity:180 Tablet(S);		Zydus Pharm
	Norvas			C				Not Reported
	Hctz			C				Not Reported
	Potassium Chloride			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Predinsdone			C				Not Reported
	Pravastatin			C				Not Reported
	General Vitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616524	EXPEDITED (15-DAY)		HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-509		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis Infective; Cat Scratch Disease; Complication Associated With Device	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Westward
	Rituximab			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616629	DIRECT		OT				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash; Visual Impairment	Hydroxychloroquine			S		Quantity:1 Tablet(S);		Sandoz
	Valsartan			C				Not Reported
	Metoprolol			C				Not Reported
	Atorvastatin			C				Not Reported
	Levothyroxine			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Apsirin			C				Not Reported
	Women'S Silver Centrum			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616815	DIRECT	Y	OT			42 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Hydroxychloroquine			S	Oral			American Health
	Atorvastatin 40mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17616895	EXPEDITED (15-DAY)		OT	NVSC2020GB089786		43 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Cutaneous Lupus Erythematosus; Cutaneous Lupus Erythematosus; Disease Progression; Madarosis; Mucosal Pain; Product Use In Unapproved Indication; Skin Plaque	Mycophenolate Mofetil			S	Unknown	1 G, Bid		Novartis
	Hydroxychloroquine			S	Transdermal	200 Mg, Qd		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17618200	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3348747-00		57 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra 100/25			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Zitromax			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17629156	DIRECT	Y				22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Hydroxychloroquine			S	Subcutaneous			Abbvie
	Humira			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	12994284	EXPEDITED (15-DAY)		OT	CA-SA-2016SA199672		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Arava			S	Oral	Unk Unk,Unk		Sanofi
	Methotrexate			S	Unknown	20 Mg,Qw		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Qw		Not Reported
	Sulfasalazine			C	Unknown	1 G, Bid		Not Reported
	Celebrex			C	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	13660454	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1724612US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actonel			S	Unknown	35 Mg, Q Week		Allergan
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	300 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 G, Cyclical		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Qd		Not Reported
	Risedronic Acid			S	Unknown	Unk		Not Reported
	Risedronic Acid			S	Unknown	35 Mg, Q Week		Not Reported
	Risedronic Acid			S	Unknown	35 Mg, Q Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	14539305	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0137			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Off Label Use; Pain; Pain;	Kineret			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Actemra			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S		Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Tocilizumab	S	Subcutaneous	Not Reported
	Gold	S	Intramuscular	Not Reported
	Imuran	S		Not Reported
	Leflunomide	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C		Not Reported
	Desoximetasone	C		Not Reported
	Cortisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15100628	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0716		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Kineret			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Apo-Azathioprine			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

				otherwise specified)	
	Imuran		S		Not Reported
	Methotrexate Sodium		S		Not Reported
	Apo-Leflunomide		S		Not Reported
	Leflunomide		S	Oral	Not Reported
	Azathioprine		S		Not Reported
	Gold		S		Not Reported
	Cimzia		S		Not Reported
	Sulfasalazine		S		Not Reported
	Arava		S		Not Reported
	Certolizumab Pegol		S		Not Reported
	Etanercept		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Oral	Not Reported
	Infliximab		S	Intravenous (not otherwise specified)	Not Reported
	Prednisone		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15108403	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0760			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Joint Swelling; Rheumatoid Arthritis	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Imuran			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Etanercept			S				Not Reported
	Methothrexate			S	Unknown			Not Reported
	Apo-Hydroxyquine			S				Not Reported

	Plaquenil	S		Not Reported
	Methotrexate Sodium	S		Not Reported
	Apo-Hydroxyquine (Hydroxychloroquine Sulfate)	S		Not Reported
	Rituxan (Rituximab)	S	Intravenous (not otherwise specified)	Not Reported
	Remicade (Infliximab)	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Vaginal	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C		Not Reported
	Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15108418	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0726		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Headache; Migraine; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection	Kineret			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Meloxicam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15619709	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555775-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Vaccine; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15620439	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556971-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15621423	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557292-00		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Contraindicated Product Administered; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Radioactive Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Prednisone	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Indometacin	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Cymbalta	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15621502	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557034-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Humira			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Apo-Azathioprine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib	C		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15622316	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557239-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Impaired Work Ability; Impaired Work Ability; Nasopharyngitis; Nasopharyngitis; Rheumatoid Arthritis; Rheumatoid Arthritis; Stress; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Vioxx			S	Oral			Not Reported
	Vioxx			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous drip	Not Reported
	Orencia	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15629333	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-ABBVIE-18K-028-2557519-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Solution		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Foa-Solution		Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S				Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

					Hydroxychloroquine		S			Not Reported
					Orencia		S	Intravenous (not otherwise specified)		Not Reported
					Hydroxychloroquine Sulfate		S	Oral		Not Reported
					Infliximab		S	Unknown		Not Reported
					Certolizumab Pegol		S	Subcutaneous		Not Reported
					Rituximab		S	Intravenous (not otherwise specified)		Not Reported
					Arava		C	Oral		Not Reported
					Orencia		C	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15662825	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ABBVIE-18K-028-2569806-00		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Arava			S	Nasal			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Ilaris			S	Subcutaneous	Ilaris Single-Use Vial		Not Reported
	Ilaris			S	Subcutaneous	Ilaris Single-Use Vial		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported

Plaquenil	S	Unknown	Not Reported
Plaquenil	S		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Sodium Aurothiomalate	S		Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S		Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S		Not Reported
Gold	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S		Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S		Not Reported
Oxyquinoline Sulfate	S	Unknown	Not Reported
Oxyquinoline Sulfate	S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15663251	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570496-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15717406	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587385-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accident; Alopecia; Bronchitis Chronic; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Neck Surgery; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Mobicox	C		Not Reported
	Remicade	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15811306	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2617216-00		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

Necrosis; Skin Ulcer			otherwise specified)	
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Alendronate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Alendronic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Ciclosporin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15930868	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655637-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

			otherwise specified)	
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Desoximetasone	C		Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Dexamethasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	15994348	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2674858-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Surgery; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16079906	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2019-05955		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Immune Globulin(Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin(Human)	S	Unknown	Unknown	Not Reported
	Immune Globulin(Human)	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Naproxen	S			Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Triamcinolone	S	Other	Unknown	Not Reported
	Triamcinolone	S	Unknown	Unknown	Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Naproxen	S			Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported

Gamastan	S	Intramuscular	Liquid Intramuscular		Not Reported
Tocilizumab	S	Unknown	Unknown		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)			Not Reported
Folic Acid	C	Unknown	Unknown		Not Reported
Triamcinolone Hexacetonide	C	Intra-articular	Unknown, Injectable Suspension		Not Reported
Triamcinolone Hexacetonide	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16444293	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822475-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Cyclical		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Enbrel	S	Subcutaneous			Not Reported
Cimzia	S	Subcutaneous			Not Reported
Anakinra	S	Subcutaneous			Not Reported
Leflunomide	S	Unknown			Not Reported
Actemra	S	Subcutaneous			Not Reported
Actonel	S	Unknown			Not Reported
Apo-Leflunomide	S	Oral	Cyclical		Not Reported
Apo-Leflunomide	S	Oral			Not Reported
Cimziasingle	S	Subcutaneous			Not Reported
Arava	S	Oral			Not Reported
Risedronate	S	Oral			Not Reported
Xeljanz	S	Oral			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Risedronate Sodium	S	Oral			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16567681	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1074636			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Back Pain; Drug Ineffective; Enthesopathy; Hla Marker Study Positive; Pancytopenia; Spinal Pain; Spondyloarthropathy; Synovial Disorder	Diclofenac Sodium			S	Unknown	150 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Naproxen			S	Unknown	1000 Milligram Daily;		Teva
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Hydroxychloroquine			C	Unknown	400 Milligram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Piroxicam			C	Unknown	20 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	20 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16686320	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-21297		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis; Walking Aid User	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported

Apo-Prednisone	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Atorvastatin	C	Unknown		Not Reported
Atorvastatin	C	Unknown	Unknown	Not Reported
Atorvastatin Calcium	C	Unknown	Unknown	Not Reported
Pantoloc	C	Unknown	Enteric-Coated	Not Reported
Pantoloc	C	Unknown		Not Reported
Pantoloc	C	Unknown	Unknown	Not Reported
Pantoprazole	C	Unknown	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unknown	Not Reported
Plaquenil	C	Oral		Not Reported
Plaquenil	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16687965	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210544		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Rheumatoid Arthritis	Arava			S		366 Unk		Sanofi
	Plaquenil			S		Unk		Sanofi
	Pregabalin			S		150 Mg		Not Reported
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		1000 Mg, Bid		Not Reported
	Orencia			S		Unk		Not Reported
	Orencia			S				Not Reported
	Xeljanz			S		Unk		Not Reported
	Rituxan			S		1000 Mg		Not Reported

	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	1000 Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	400 Mg	Not Reported
	Trazodone	C		200 Mg, Qd	Not Reported
	Lumigan Rc	C	Ophthalmic	1 Df, Qd	Not Reported
	Suphedrine [Pseudoephedrine Hydrochloride]	C		10 Mg, Qd	Not Reported
	Tylenol [Paracetamol]	C		Unk	Not Reported
	Tylenol [Paracetamol]	C		3000 Mg, Qd	Not Reported
	Valsartan	C		1 Df, Qd	Not Reported
	Valsartan	C		Unk	Not Reported
	Wellbutrin	C		300 Mg, Qd	Not Reported
	Esomeprazole	C		40 Mg, Qd	Not Reported
	Nexium [Esomeprazole Sodium]	C		40 Mg, Qd	Not Reported
	Tylenol Extra Strength	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16710864	EXPEDITED (15-DAY)		DS, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2019VAL000394		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Demerol			S	Unknown	Unk		Validus
	Plaquenil /00072602/			S	Oral	400 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported

	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Levofloxacin	S	Unknown	Unk	Not Reported
	Norfloxacin	S	Unknown	400 Mg, Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Cefaclor	S	Unknown	Unk	Not Reported
	Celecoxib	S	Oral	200 Mg, Qd	Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Meperidine /00016301/	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16718490	EXPEDITED (15-DAY)		OT	CA-SA-2019SA216804		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Prednisone			C	Unknown	1 Df, Qd (5 Mg)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16720242	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217291			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Joint Swelling; Ocular Toxicity; Rheumatoid Arthritis	Arava			S	Oral	10 Mg, Qd		Sanofi
	Diclofenac			S	Unknown	50 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd (Prior To 2011)		Sanofi
	Indometacin			S		50 Mg, (20 To 50 Mg) Tid		Not Reported
	Leflunomide			S	Oral	10 Mg, Qd (Prior To 2016)		Sanofi
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Methotrexate			S	Oral	15 Mg, (10 To 15 Mg) Qw (Prior To 2011)		Not Reported
	Naproxen			S	Unknown	500 Mg, Q6h		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	16923698	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2019VAL000576			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Demerol			S	Unknown	Unk		Validus
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S		Unk		Not Reported
	Diphenhydramine Hydrochloride			S		Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported

	Cyclophosphamide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Azithromycin	S	Unknown	250 Mg, Qd	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Imuran /00001502/	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Unk	Not Reported
	Xeljanz	S	Oral	5 Unk	Not Reported
	Ezetrol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17199927	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3206389-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intestinal Perforation; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17559399	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018-03346		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown. Powder For Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown	Unknown Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown. Solution		Not Reported
	Gold			S	Intramuscular	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Methotrexate Sodium			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported

Orencia	S	Unknown	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Rituximab	S	Unknown	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
Sulfasalazine	C	Unknown	Unknown		Not Reported
Wellbutrin	C	Unknown	Unknown		Not Reported
Xeljanz	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17559777	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008882			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17571111	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008956		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Q.O.Wk.		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported

Methotrexate	S	Oral	20 Mg, Q.Wk.		Not Reported
Methotrexate	S	Oral	12.5 Mg, Unk		Not Reported
Methotrexate	S	Oral	12.5 Mg, Qd		Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Qd		Not Reported
Methotrexate	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Mg, Unk, 1 Every 4 Weeks		Not Reported
Orencia	S	Unknown	500 Mg, Unk, 1 Every 4 Weeks		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17575454	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008927		77 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diabetes Mellitus; Drug Ineffective; Drug Intolerance	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	200 Mg, Qd		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	20 Mg, Qd		Not Reported
	Simponi			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17591358	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009095		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported
Supeudol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17611780	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002282			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17611784	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002283			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17611792	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002284			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17618992	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003001932			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Eye Injury; Fatigue; Headache; Therapeutic Response Delayed; Therapeutic Response Shortened; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	Unk (Or, Dose, Frequency, Route Lot Number And Expiry Date Unknown)		Not Reported
	Actemra			S	Unknown	Unk (Suspended On 25-Feb-2020)		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Humira			C		Unk		Not Reported
	Enbrel			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Pantoloc			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17619006	EXPEDITED (15-DAY)		DS	CA-ADVANZ PHARMA-202003001934			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Diarrhoea; Drug Ineffective; Liver Disorder; Loss Of Personal Independence In Daily Activities; Oral Herpes	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			C				Not Reported
	Orencia			C				Not Reported
	Methotrexate			C		Unk		Not Reported
	Voltaren			C		Unk		Not Reported
	Leucovorin			C		Unk		Not Reported
	Iron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17620210	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009225		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Cataract; Contraindicated Product Administered; Dermatitis Allergic; Drug Ineffective; Drug Intolerance; Hepatotoxicity; Nasopharyngitis; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Treatment Failure; Urticaria	Leflunomide			S	Oral	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Sulfasalazine			S	Unknown	750 Mg, Qd		Not Reported
	Hydrochlorothiazide W/Lisinopril			C	Unknown	Unk		Not Reported
	Hydrochlorothiazide W/Lisinopril Dihydrate			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported
	Rituxan			C	Unknown	Unk		Not Reported
	Tylenol Extra Strength			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17620330	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002212			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Infection; Skin Lesion	Hydroxychloroquine			S		400 Mg, Qd		Concordia
	Hydroxychloroquine			S				Concordia
	Aminosalicylic Acid			S		81 Mg, Qd		Not Reported
	Aminosalicylic Acid			S				Not Reported
	Mycophenolate Mofetil			S		1 G, Qd		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Quinacrine			C		100 Mg, Qd		Not Reported
	Quinacrine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17620886	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1493			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Ankylosing Spondylitis; Condition Aggravated; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Off Label Use; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Kineret			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown	2.5 Mg 1 Every 2 Weeks		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622122	EXPEDITED (15-DAY)		OT	CA-ROCHE-2573031			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Eye Injury; Fatigue; Headache; Liver Disorder; Therapeutic Product Effect Decreased;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Ulcer Haemorrhage	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	20 Mg Was Reduced To 7.5 Mg	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Pantoloc [Pantoprazole]	C			Not Reported
	Humira	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622228	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217086			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622407	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217045		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Diclofenac			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Diclofenac			S	Unknown			Actavis
	Amitriptyline			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Teva
	Celecoxib			S	Unknown			Teva
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Intravenous (not otherwise specified)			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Naproxen			S	Unknown			Teva
	Pregabalin			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Amitriptyline Hydrochloride/Perphenazine			S	Unknown			Not Reported
	Apo-Amitriptyline			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Diclofenac			S	Topical			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Apo-Naproxen	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Celebrex	S	Unknown		Not Reported
Celebrex	S	Unknown		Not Reported
Diclofenac Sodium/Misoprostol	S	Unknown		Not Reported
Enbrel	S	Subcutaneous	7.1429 Milligram Daily;	Not Reported
Etanercept	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulphate	S	Unknown		Not Reported
Hydroxychloroquine Sulphate	S	Unknown		Not Reported
Lyrica	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S			Not Reported
Misoprostol	S	Unknown		Not Reported
Naprosyn [Naproxen	S	Unknown		Not Reported
Nifedipine	S	Unknown		Not Reported
Orencia	S	Subcutaneous	107.1429 Milligram Daily;	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Winpred	S	Unknown		Not Reported
Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
Tofacitinib	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622559	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217497			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density	Meloxicam			S	Unknown			Not Reported

Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Leflunomide	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Actemra	S	Subcutaneous		Not Reported
	Arava	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Depo-Medrol	C	Intra-articular	80 Milligram Daily;	Not Reported
	Humira	C	Subcutaneous		Not Reported
	Diclofenac	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622669	EXPEDITED (15-DAY)		OT	CA-SA-2020SA079660			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Leukopenia	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Codeine			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported
	Humira			C				Not Reported
	Orencia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17622915	DIRECT	Y	HO			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Pancytopenia	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17623040	DIRECT	Y	OT			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17623288	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-05347		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Advil			C	Unknown	Unknown		Not Reported
	Folic Acid			C	Unknown	Unknown		Not Reported
	Ketorolac			C	Unknown	Unknown		Not Reported

	Methotrexate		C	Unknown		Not Reported
	Naproxen		C	Unknown	Unknown	Not Reported
	Prednisone		C	Unknown	Unknown	Not Reported
	Xeljanz		C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17623349	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1578		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17623403	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342132		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness;	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17624098	EXPEDITED (15-DAY)		HO, OT	NVSC2020US090011		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Cardiomyopathy; Cardiotoxicity; Dyspnoea Exertional; Orthopnoea; Peripheral Swelling	Hydroxychloroquine			S	Unknown	200 Unk, Bid		Novartis
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17624253	EXPEDITED (15-DAY)		OT	CA-EMD SERONO-E2B_90076287		28 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anovulatory Cycle; Bronchitis; Dermatomyositis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased; Malaise; Nasopharyngitis;	Metformin Hydrochloride			S	Unknown	Unknown		Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported
	Cymbalta			S	Unknown	Unknown Dosage		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Plaquenil /00072602/			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported

Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder; Weight Increased	Rituxan		S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine		S	Unknown	Unknown	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Imuran /00001501/		C	Unknown	Unknown	Not Reported
	Xarelto		C	Unknown	Unknown	Not Reported
	Azathioprine Sodium		C	Unknown		Not Reported
	Methotrexate		C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17624589	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-009614			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Intra-arterial	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17625486	EXPEDITED (15-DAY)		HO, LT, OT	MX-ACCORD-178039		29 YR	Female	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Endophthalmitis; Liver Abscess; Muscle Abscess; Myositis; Nocardiosis; Off Label Use; Perinephric Abscess; Pneumonia; Pyomyositis	Mycophenolic Acid			S	Oral			Accord
	Hydroxychloroquine			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17625490	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-		54 YR	Female	FRA

2020RR-242736

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Headache; Palpitations	Risedronate			S	Oral	35 Milligram, In Total		Sun
	Plaquenil			S	Oral	1 Dosage Form, Daily		Not Reported
	Cortancyl 20 Mg, Comprime			S	Oral	()		Not Reported
	Pantoprazole			C	Unknown	()		Not Reported
	Izalgi 500 Mg/25 Mg, Gelule			C	Unknown	()		Not Reported
	Levothyrox 75 Microgrammes, Comprime Secable			C	Unknown	()		Not Reported
	Diffu K, Gelule			C	Unknown	()		Not Reported
	Atorvastatine			C	Unknown	()		Not Reported
	Clopidogrel (Chlorhydrate De)			C	Unknown	()		Not Reported
	Procoralan 5 Mg, Comprime Pellicule			C	Unknown	()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2020	16162286	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2733052-00		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Contraindicated Product Administered; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2020	17625695	EXPEDITED (15-DAY)		DE	IE-ABBVIE-20K-229-3352301-00		57 YR	Female	IRL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Completed Suicide; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Mabthera			S	Unknown			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported
	Seroquel			C				Not Reported
	Arava			C				Not Reported
	Depo-Medrone			C				Not Reported
	Sodium Aurothiomalate			C				Not Reported
	Methotrexate			C				Not Reported
	Protium			C				Not Reported
	Valdoxan			C				Not Reported
	Alendronate			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Prednisolone			C				Not Reported
	Sulfasalazine			C				Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2020	17625752	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217530		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown			Not Reported
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported

	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	10991568	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20150323608		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Swelling; Synovitis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	14535486	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-BIOVITRUM-2018CA0124		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Apo Sulfasalazine Tab 500mg			S				Not Reported
	Apo Sulfasalazine Tab 500mg			S				Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported

Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate Sodium	S		Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Ilaris Single-Use Vial	S		Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S		Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Cannabis Sativa	S		Not Reported
	Lyrica	S		Not Reported
	Oxycodone	S		Not Reported
	Minocycline Hydrochloride	S		Not Reported
	Rituximab	S	Unknown	Not Reported
	Minocycline	S		Not Reported
	Oxyquinoline Sulfate	S		Not Reported

Xeljanz	S			Not Reported
Urelumab	C	Unknown		Not Reported
Kineret	C			Not Reported
Lyrica	C	Oral		Not Reported
Plaquenil	C			Not Reported
Prednisone	C			Not Reported
Rituximab	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	14535544	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0125		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Kineret			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	Dose: 12.5 Mg Once Daily		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Dose. 12.5 Mg 1x1 Daily		Not Reported
	Methotrexate Sodium			S	Oral	Dose: 12.5 Mg		Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15066519	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0720		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Kineret			S				Not Reported
	Actemra			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S				Not Reported
	Gold			S	Subcutaneous			Not Reported
	Ilaris			C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15100606	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0751		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported

	Infliximab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Prednisone	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tocilizumab	S		Not Reported
	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C		Not Reported
	Desoximetasone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15407353	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180911920		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Back Pain; Contraindicated Product Administered; Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Pain; Pain In Extremity; Pain In Jaw; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Leflunomide	S	Oral	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15620412	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556731-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported

	Plaquenil	S	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15625609	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-18K-028-2557423-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis;	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Apo-Cyclosporine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Not Reported
	Infliximab			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Endocervical	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Apo-Ibuprofen	S	Oral	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apremilast	S		Not Reported
	Motrin	S	Oral	Not Reported
	Motrin	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Cyclosporine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Ibuprofen	S	Oral	Not Reported
	Colchicine	C	Oral	Not Reported
	Folic Acid	C		Not Reported
	Nitrazepam	C	Oral	Not Reported
	Oxycodone	C		Not Reported
	Uloric	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C		Not Reported
	Benadryl	C		Not Reported

	Dexilant	C	Oral		Not Reported
	Febuxostat	C			Not Reported
	Gravol	C			Not Reported
	Mogadon	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15674250	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573605-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Drug Intolerance; Joint Swelling; Polyarthritis; Synovitis; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S				Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Actemra			C				Not Reported
	Bisoprolol			C				Not Reported
	Candesartan			C				Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported
	Sulfamethoxazole/Trimethoprim			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15678194	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574920-00		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Fluctuation; Blood Pressure Increased; Blood	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Pressure Systolic Increased; Colitis; Contraindicated Product Administered; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastric Disorder; Gastrointestinal Disorder; Haematochezia; Hypertension; Joint Swelling; Musculoskeletal Stiffness; Nausea; Oxygen Saturation Decreased; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Decreased; Weight Increased	Diamicron	S	Unknown		Not Reported
	Gliclazide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous drip		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Asacol	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	225.0	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Norvasc	S	Oral		Not Reported
	Norvasc	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Aerius	C			Not Reported
	Crestor	C			Not Reported
	Diphenhydramine	C	Oral		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Amlodipine Besilate	C	Unknown		Not Reported
	Atacand Plus	C			Not Reported
	Bisoprolol Fumarate	C			Not Reported
	Depo-Medrol	C	Intra-articular		Not Reported
	Ferrous Gluconate	C			Not Reported
	Folic Acid	C			Not Reported

Tylenol	C		Not Reported
Vitamin D3	C		Not Reported
Rosuvastatin Calcium	C		Not Reported
Ebastine	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15702726	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2580931-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15707673	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2584580-00		84 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Injury; Drug Ineffective; Fall; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15733752	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594187-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Minocyclin			S	Unknown			Not Reported
	Apo-Minocyclin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported
	Xeljanz	C	Unknown	Not Reported
	Hydroxychloroquine	C	Ophthalmic	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15734078	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594192-00		62 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15734387	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594151-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Contraindicated Product Administered; Drug Intolerance; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Xeljanz	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Lyrica	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15739251	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594156-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Varilrix			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Unknown	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
	Cortisone Acetate	C	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Subcutaneous	Not Reported
	Diclofenac	C	Subcutaneous	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15930738	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655654-00		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Topicort			S	Unknown			Not Reported
	Glumetza			S	Unknown			Not Reported
	Altace			C	Unknown			Not Reported
	Asa			C				Not Reported
	D-Alpha Tocopherol			C				Not Reported
	Folic Acid			C	Unknown	1.0		Not Reported
	Methotrexate			C	Oral			Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported

Vitamin D	C	Unknown	Not Reported
Docosahexaenoic Acid	C		Not Reported
Eicosapentaenoic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	15958056	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170820946		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Contraindication To Vaccination; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Laryngeal Disorder; Nausea; Off Label Use; Pain; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	0.8 Ml		Not Reported
	Humira			S	Subcutaneous	0.8 Ml		Not Reported
	Humira			S	Subcutaneous	0.8 Ml		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

Certolizumab	S	Subcutaneous	Not Reported
Azathioprine	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Lyrica	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Cellcept /01275102/	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Pregabaline	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Piroxicam	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16040473	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1020190			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Meloxicam			S	Unknown			Teva
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Mobicox	S	Unknown	Not Reported
	Orencia	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16301153	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121523			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16381114	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2804954-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis;	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported

Unevaluable Event; Urticaria	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Amlodipine	C		Not Reported
	Arava	C		Not Reported
	Benadryl	C		Not Reported
	Naproxen	C		Not Reported
	Prednisone	C		Not Reported
	Tofacitinib Citrate	C		Not Reported
	Viread	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16441274	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2822469-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Contraindicated Product Administered; Drug Intolerance; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Lyrica			C	Unknown			Not Reported

	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16443280	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2819775-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16497972	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019026465			Female	CAN

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

Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Cimzia	S	Subcutaneous		Not Reported
	Acetaminophen	S	Endocervical		Not Reported
	Actemra	S			Not Reported
	Arava	S		20 Milligram, Once Daily (Qd)	Not Reported
	Arava	S		10 Milligram, Once Daily (Qd)	Not Reported
	Enbrel	S		50 Milligram, Weekly (Qw)	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulphate	S		200 Milligram, 2x/Day (Bid)	Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	500 Milligram, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, 2x/Day (Bid)	Not Reported
	Methotrexate	C		Unk, Weekly (Qw)	Not Reported
	Meloxicam	C			Not Reported
	Synthroid	C			Not Reported
	Acetaminophen And Codeine Phosphate	C			Not Reported
	Apo-Prednisone	S	Oral	20 Nanogram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S		200 Milligram, 2x/Day (Bid)	Not Reported
	Codeine	C			Not Reported
	Tylenol [Paracetamol]	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16714535	EXPEDITED (15-DAY)		OT	CA-SA-2019SA216686			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Celebrex			C				Not Reported
	Lyrica			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16717736	EXPEDITED (15-DAY)		OT	CA-SA-2019SA216698		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Metals; Arthralgia; Cerebral Disorder; Condition Aggravated; Cystitis; Disturbance In Attention; Drug Intolerance; Gait Disturbance; Grip Strength Decreased; Hypersensitivity; Intentional Product Use Issue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased;	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Ibuprofen			S	Oral	400 Mg 3-4/Day		Not Reported
	Methotrexate			S		25 Mg, Qw		Not Reported
	Hydroxychloroquine			S				Sanofi
	Gold			S	Intramuscular	10 Mg, 1x		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

Musculoskeletal Stiffness; Pneumonitis; Therapeutic Product Effect Incomplete

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17156996	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191212448			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Reactine (Cetirizine Hydrochloride)			S	Unknown			Johnson And Johnson
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Johnson And Johnson
	Cetirizine Hydrochloride			S	Unknown			Johnson And Johnson
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Johnson And Johnson
	Pseudoephedrine Hydrochloride			S	Unknown			Johnson And Johnson
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Janssen
	Actemra			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

Methotrexate	S	Oral			Not Reported
Methotrexate	S	Intra-arterial			Not Reported
Methotrexate Sodium	S	Unknown			Not Reported
Orencia	S	Subcutaneous			Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Plaquenil /00072602/	S	Unknown			Not Reported
Prednisone	S	Oral			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
Sulfasalazine	S	Subcutaneous			Not Reported
Simponi	S	Subcutaneous			Janssen
Xeljanz	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17173636	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053782			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous			Ucb
	Cetirizine Hydrochloride			S		Unk		Ucb
	Cetirizine Hydrochloride			S				Ucb
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Pseudoephedrine Hydrochloride			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Apo-Prednisone			S				Not Reported

Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Desoximetasone	S	Oral		Not Reported
Diclofenac Sodium	S			Not Reported
Etanercept	S	Subcutaneous		Not Reported
Folic Acid	S		1 Milligram	Not Reported
Folic Acid	S		5 Milligram	Not Reported
Folic Acid	S		1 Milligram	Not Reported
Folic Acid	S		5 Milligram	Not Reported
Fosamax	S	Oral		Not Reported
Fosamax	S	Oral		Not Reported
Adalimumab	S	Subcutaneous	40 Milligram Solution	Ucb
Hydroxychloroquine	S			Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Methotrexate	S	Oral	Solution	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram Solution	Not Reported
Methotrexate Sodium	S			Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S			Not Reported
Prednisone	S	Oral		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Subcutaneous	500 Milligram	Not Reported
Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17200098	EXPEDITED (15-DAY)		OT	SE-ADVANZ PHARMA-201912003018			Unknown	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Lupus Erythematosus; Drug Ineffective	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Bid ,1 Tablet Twice A Day For 2 Weeks		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form		Concordia
	Trombyl			C		75 Mg		Not Reported
	Candesartan			C		16 Mg		Not Reported
	Levaxin			C		25 Mg		Not Reported
	Methotrexate			C		Unk		Not Reported
	Dermovate			C		Unk		Not Reported
	Omeprazol			C		Unk		Not Reported
	Rosuvastatin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17350398	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020003181			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		50 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S		25 Milligram, Weekly (Qw)		Not Reported
	Leflunomide			S				Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported

	Sulfasalazine	S	1 Gram, 2x/Day (Bid)	Not Reported
	Hydroxychloroquine Sulfate	S	400 Milligram, Once Daily (Qd)	Not Reported
	Xeljanz	C	5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	C	11 Milligram, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17391221	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170826218		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Distension; Abdominal Distension; Adverse Reaction; Arthralgia; Coeliac Disease; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Dyspepsia; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nail Disorder; Nausea; Off Label Use; Onychomycosis; Pain; Product Use In	Stelara			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Otezla			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S				Not Reported

Unapproved Indication; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sleep Disorder; Treatment Failure	Salazopyrin	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Tocilizumab	S		Not Reported
	Orencia	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Apo Prednison	S	Oral	Not Reported
	Rheumatrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17420592	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0792		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Kineret			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

				otherwise specified)	
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Oral	Not Reported
	Desoximetasone		C	Unknown	Not Reported
	Methotrexate		C	Oral	Not Reported
	Prednisone		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17425017	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0812		40 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Kineret			S				Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17563093	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20170105863			Female	CAN

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

Abdominal Discomfort; Adjustment Disorder With Depressed Mood; Alopecia; Amnesia; Contraindicated Product Administered; Delirium; Diabetes Mellitus; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Gait Disturbance; Glossodynia; Grip Strength Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; Maternal Exposure During Pregnancy; Mobility Decreased; Muscular Weakness; No Adverse Event; Pain; Pain In Extremity; Pemphigus; Peripheral Swelling; Product Use Issue; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Walking Aid User; Weight Decreased; Wound Infection	Simponi	S	Subcutaneous	Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Cosentyx	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported

	W/Tri/00005601/				
	Reactine /00884302/	S	Unknown		Not Reported
	Naprosyn /00256201/	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17579775	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327856		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Gold			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17580328	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0808		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported

Product Effect Incomplete; Treatment Failure	Cimzia	S	Subcutaneous		Not Reported
	Dextromethorphan Hydrobromide	S	Unknown		Not Reported
	Eletriptan Hydrobromide	S			Not Reported
	Eletriptan Hydrobromide	S			Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	0.75 Mg Once Monthly	Not Reported
	Rituximab	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz Xr	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Every 1 Month	Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Azathioprine	S			Not Reported
	Celebrex	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Celecoxib	S	Unknown		Not Reported
	Celecoxib	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Plaquenil	S			Not Reported
	Prednisone	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported

Prednisone	S	Unknown		Not Reported
Remicade	S			Not Reported
Simponi	S			Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Calcium	C	Oral		Not Reported
Dilaudid	C	Unknown		Not Reported
Dilaudid	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Hydromorph Contin	C	Unknown		Not Reported
Hydromorph Contin	C	Unknown		Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Apo-Gabapentin	C	Oral		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Atorvastatin Calcium	C	Oral		Not Reported
Atorvastatin Calcium	C	Oral		Not Reported
Cipralex	C	Unknown		Not Reported
Citalopram Hydrobromide	C	Unknown		Not Reported
Conjugated Estrogens	C	Unknown	Dose: 0.625 Mg	Not Reported
Conjugated Estrogens	C	Unknown		Not Reported
Escitalopram	C	Unknown		Not Reported
Estrace	C	Unknown	Dose: 0.5 Mg	Not Reported
Gabapentin	C	Oral		Not Reported
Gabapentin	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported

Cymbalta	C	Unknown			Not Reported
Hydrochlorothiazide	C	Unknown	Dose: 12.5 Mg		Not Reported
Hydromorphone Hcl	C	Oral			Not Reported
Hydromorphone Hcl	C	Oral			Not Reported
Mupirocin	C	Topical			Not Reported
Pantoloc	C	Unknown			Not Reported
Shark Liver Oil	C	Unknown			Not Reported
Tapentadol Hydrochloride	C	Unknown			Not Reported
Taro-Mupirocin	C	Topical			Not Reported
Tramacet	C	Oral			Not Reported
Tramadol Hydrochloride	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17583318	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202003001754			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis Infective; Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Erythema; Inflammation; Pneumonia; Purulence; Pyrexia; Tenderness	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628411	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202003002097			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Hydroxychloroquine			S	Unknown	400 Mg 2x15 Cprrev, Plaquinol, Film-Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628438	EXPEDITED (15-DAY)		HO	FR-ADVANZ PHARMA-202003002241			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Fibromyalgia; Malaise; Pleural Effusion	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form,Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628439	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202003002041			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Hydroxychloroquine			S	Unknown	Unk, (Coated Tablets)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628622	EXPEDITED (15-DAY)		DS, OT	FR-ADVANZ PHARMA-202003002294			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiovascular Disorder; Chronic Obstructive Pulmonary Disease; Diabetes Mellitus; Infection; Pneumonia; Respiratory Distress; Wheelchair User	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk (Film-Coated Tablet)		Concordia
	Cortancyl			C		Unk		Not Reported
	Vitamin D [Vitamin D Nos]			C		Unk		Not Reported
	Calcium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628632	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3352546-00			Female	CAN

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

Drug Hypersensitivity; Rheumatoid Arthritis	Humira	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628737	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009312			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Joint Swelling; Rheumatoid Arthritis	Leflunomide			S	Oral	Unk		Apotex
	Plaquenil /00072602/			S	Oral	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17628958	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014088		82 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Candida Infection; Oral Pain; Oropharyngeal Pain; Stomatitis	Cimzia			S	Subcutaneous	200 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2x/Day (Bid)		Not Reported
	Methotrexate			S	Subcutaneous	200 Milligram		Not Reported
	Benzylhydrochlorothiazide			C				Not Reported
	Coumadin			C				Not Reported
	Cyanocobalamin			C				Not Reported

	Eltroxin	C		Not Reported
	Metoprolol	C		Not Reported
	Pravachol	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629123	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2020014089			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Etanercept			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Tocilizumab			S		160 Milligram		Not Reported
	Azathioprine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629213	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002163			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Condition Aggravated; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629297	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217561			Female	CAN

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

Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Barr
	Prednisone	S	Unknown	Actavis
	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629303	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217500		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung;	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Oral			Not Reported

Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629306	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217468			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Barr
	Diclofenac Sodium			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629352	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217523			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Humira			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629366	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217536			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength	Meloxicam			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported

Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Sulfasalazine	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629396	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217963		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629398	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218003			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Subcutaneous			Barr

Fatty Liver Disease; Pruritus; Treatment Failure	Azathioprine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Barr
	Actemra	S	Subcutaneous	23.1429 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Kevzara	S	Subcutaneous		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Magnesium	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629401	NON-EXPEDITED			US-AMGEN-USASP2020048450		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, ((0, 2, 6 Wks, Then Every 8 Wks.)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram, (Every 8 Weeks)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram, (Every 7 Weeks)		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Otrexup			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629497	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003001847			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Height Decreased; Drug Tolerance Increased; Hypoacusis; Joint Injury; Joint Swelling; Migraine; Musculoskeletal Disorder; Therapeutic Product Effect Decreased; Vomiting	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid, One In The Morning One In Night		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17629815	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002043			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure During Pregnancy; Gestational Diabetes; Shortened Cervix	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17630225	EXPEDITED (15-DAY)		OT	NVSC2020CA090993			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Transaminases Increased	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	10 Mg, Unknown		Not Reported
	Leflunomide			S	Unknown	20 Mg, Unknown		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17631124	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3352969-00		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia; Hypocoagulable State	Kaletra			S	Oral			Not Reported
	Hidroxicloroquina			S	Oral	200 Mg/12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17631943	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217985		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632010	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318931			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Nausea; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Treatment Failure; Urticaria	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Mefenamic Acid			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Arthrotec			C	Oral			Not Reported
	Tylenol /00020001/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632057	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217417			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue;	Alendronate Sodium			S	Oral			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Intra-arterial	25 Mg		Barr

Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate	S	Unknown	Barr
	Prednisone	S	Oral	Actavis
	Prednisone	S	Unknown	Actavis
	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632099	NON-EXPEDITED		OT	NVSC2020US092034		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Diastolic Dysfunction	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632120	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217560			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral	7.5 Mg		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S		20 Millimol Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632164	EXPEDITED (15-DAY)		OT	NVSC2020FR079225		53 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acarodermatitis; Ocular Toxicity	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Belimumab			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632212	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014049		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Apo-Azathioprine			S				Not Reported
	Arava			S		Unk		Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Cephalexin Monohydrate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632213	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014044		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity;	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S				Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form, Weekly (Qw)		Not Reported
	Glumetza			S		500 Milligram, 2x/Day (Bid)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S				Not Reported

Peripheral Swelling; Therapeutic Product Effect Decreased	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S			Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Acetaminophen	C			Not Reported
	Altace	C			Not Reported
	Arava	C			Not Reported
	Asa	C			Not Reported
	Codeine	C			Not Reported
	D-Alpha Tocopherol	C			Not Reported
	Ergocalciferol	C			Not Reported
	Folic Acid	C			Not Reported
	Prednisone	C	Oral		Not Reported
	Rosuvastatin Calcium	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632322	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632341	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217513			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632490	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-2014318US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Epistaxis; Headache; Insomnia; Nausea; Osteonecrosis Of Jaw; Transaminases Increased	Risedronate Sodium Unk			S	Oral	35 Mg, Q Week		Allergan
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Mycophenolate Mofetil			S	Oral	500 Mg, Bid		Not Reported
	Mycophenolate Mofetil			S	Oral	1 G, Bid		Not Reported

	Plaquenil	S	Unknown	300 Mg, Qd	Not Reported
	Azathioprine	C	Oral	50 Mg, Qd	Not Reported
	Azathioprine	C	Oral	150 Mg, Qd	Not Reported
	Azathioprine	C	Oral	100 Mg, Bid	Not Reported
	Humira	C	Subcutaneous	40 Mg, Q2weeks	Not Reported
	Ketoprofen	C	Unknown	Unk	Not Reported
	Methotrexate	C	Oral	Unk	Not Reported
	Methotrexate	C	Subcutaneous	25 Mg, Q Week	Not Reported
	Prolia	C	Subcutaneous	Actual: 60 Mg, Every 6 Months	Not Reported
	Rituximab	C	Intravenous (not otherwise specified)	1 G, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632612	EXPEDITED (15-DAY)		OT	CA-SA-2020SA073892			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatic Fibrosis; Therapeutic Response Decreased	Leflunomide			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17632859	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217558			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect	Meloxicam			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

Decreased; Treatment Failure	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral	2.8571 Milligram Daily;	Not Reported
	Sulfasalazine	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633310	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217525		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown	22.8571 Milligram Daily;		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Other			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633436	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217998			Female	CAN

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

Anaphylactic Reaction; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Ciclosporin	S	Unknown	Ivax
	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Gabapentin	C	Unknown	Not Reported
	Tylenol Arthritis Pain 8h	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633463	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217508			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown	200 Milligram Daily;		Not Reported
	Actemra			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633465	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217531			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Depo-Medrol			C				Not Reported
	Diclofenac			C				Not Reported
	Humira			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	17633498	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160217144			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Carpal Tunnel Syndrome; Drug Ineffective; Hip Fracture;	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Intervertebral Disc Disorder; Nausea; Rheumatoid Arthritis; Stress Fracture; Vomiting	Simponi	S	Subcutaneous	Janssen
	Simponi	S		Janssen
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	14299100	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2017050873			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Contraindicated Product Administered; Drug Ineffective; Foot Deformity; Loss Of Consciousness; Mobility Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Gold	S	Unk		Not Reported
	Plaquenil	S	Oral		Not Reported
	Methotrexate	C	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	14535636	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0135			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Arthritis; Treatment Failure	Kineret			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Apo Hydroxyquine			S				Not Reported
	Apo-Mycophenolate			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
	Celebrex			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S				Not Reported
	Cellcept			S				Not Reported
	Gold			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			C				Not Reported
	Celebrex			C	Unknown			Not Reported
	Humira			C				Not Reported

	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	15624086	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557445-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	15679987	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2573622-00			Female	CAN

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

Arthropathy; Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis; Weight Increased; Wheelchair User	Humira	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Indometacin	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Morphine Sulfate	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Statex (Morphine Sulfate)	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Statex	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	15711682	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587778-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Other	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Parenteral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Imuran	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	16182582	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2738227-00		74 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Off Label Use; Pain; Product Use Issue; Rheumatoid Arthritis; Sciatica	Humira			S	Subcutaneous			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine			S	Subcutaneous			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported

Ramipril	S	Unknown	Not Reported
Codeine	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Ramipril	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Codeine Phosphate	S	Unknown	Not Reported
Cosopt	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Levothyroxine Sodium	S	Unknown	Not Reported
Altace	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Acetaminophen	S	Unknown	Not Reported
Acetaminophen W/Codeine Phosphate	C	Intravenous (not otherwise specified)	Not Reported
Tylenol No.2	C	Unknown	Not Reported
Acetaminophen W/Caffeine	C	Unknown	Not Reported
Plaquenil	C		Not Reported
Acetaminophen/Caffeine/Codeine Phosphate	C		Not Reported
Caffeine W/Dihydrocodeine Bitartrate/Paraceta	C		Not Reported
Caffeine	C		Not Reported
Dorzolamide Hydrochloride/Timololmaleate	C	Ophthalmic	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	16805717	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2921109-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	16822887	EXPEDITED (15-DAY)		HO, OT	BR-GLAXOSMITHKLINE-BR2019GSK067189		25 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Dermatitis; Headache; Herpes Zoster; Inappropriate Schedule Of Product Administration; Leukocytosis; Product Availability Issue; Product Dose Omission; Pyrexia;	Belimumab			S		Unk		Glaxosmithkline
	Belimumab			S		Unk		Glaxosmithkline
	Belimumab			S		630 Mg, Unk		Glaxosmithkline
	Mycophenolate Sodium			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

Rash; Skin Injury; Skin Lesion; Systemic Lupus Erythematosus; Urinary Tract Infection; Weight Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17257461	EXPEDITED (15-DAY)		DS, HO, OT	NVSC2020AU004219			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Ageusia; Arthralgia; Depression; Dna Antibody Negative; Drug Interaction; Fibromyalgia; Gait Disturbance; Liver Function Test Abnormal; Migraine; Nausea; Panic Attack; Paraesthesia; Psoriasis; Psoriatic Arthropathy; Respiratory Syncytial Virus Infection; Sleep Disorder; Suicidal Ideation; Systemic Lupus Erythematosus; Tachyarrhythmia; Type 1 Diabetes Mellitus; Urinary Tract Infection; Viral Tonsillitis	Mycophenolate Mofetil			S	Oral	500 Mg, Tid		Novartis
	Mycophenolate Mofetil			S				Novartis
	Methotrexate			S	Subcutaneous	10 Mg, Biw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Biw		Not Reported
	Methotrexate			S	Subcutaneous	10 Unk, Biw (Mcg)		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Rosuvastatin			S	Unknown	10 Mg		Not Reported
	Ezetimibe			S	Unknown	10 Mg		Not Reported
	Ramipril			S	Unknown	Unk Mg, Unknown (5-10)		Not Reported
	Topiramate			S	Unknown	200 Mg, Unknown		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	5-Methyltetrahydrofolate			S	Unknown	Unk		Not Reported
	Oxycontin			S	Oral	10 Mg, Bid		Not Reported
	Endone			S	Oral	5 Mg, Qd		Not Reported
	Aspirin			S	Unknown	100 Mg, Unknown		Not Reported
	Prasugrel			S	Unknown	10 Mg, Qd		Not Reported
	Ivabradine			S	Unknown	7.5 Mg, Bid		Not Reported
	Sildenafil			S	Oral	12.5 Mg, Prn		Not Reported
	Gtn			S	Oral	Unk		Not Reported
	Cannabis Sativa Oil			S	Unknown	Unk		Not Reported

Reboxetine	S	Unknown	4 Mg, Bid		Not Reported
Cholecalciferol	S	Unknown	50 Unk, Qd (Mcg)		Not Reported
Novorapid	S	Subcutaneous	Unk (Pump With Continuous Bgl Monitor)		Not Reported
Glucagen Hypokit	S	Unknown	Unk		Not Reported
Mirena	S	Unknown	52 Mg, Unknown		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg, Biw		Not Reported
Prednisolone	S	Unknown	Unk		Not Reported
Hydroxychloroquine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17374357	NON-EXPEDITED			US-PFIZER INC-2020048790		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17394735	EXPEDITED (15-DAY)		OT	RU-ADVANZ PHARMA-202002000642			Unknown	RUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd (Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	2 Dosage Form, Qd (Tablet) (Increased The Dose)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17433128	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0819		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17450107	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-BIOVITRUM-2020CA0815		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition	Kineret			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported

Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use In Unapproved Indication; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Adalimumab	S	Subcutaneous		Not Reported
	Adalimumab	S			Not Reported
	Apo-Naproxen	S			Not Reported
	Apo-Naproxen	S			Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg 1x1 Daily	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	12.5 Mg 1x1 Daily	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immunoglobulins (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)		Not Reported
	Immunoglobulins (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)		Not Reported
	Immunoglobulins (Immunoglobulin Human Normal)	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported

Naproxen Sodium	S	Unknown		Not Reported
Naproxen Sodium	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Prednisone	S	Oral	1.3 Mg 2x1 Daily	Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S			Not Reported
Triamcinolone	S	Subcutaneous		Not Reported
Triamcinolone	S	Intra-articular		Not Reported
Triamcinolone	S	Unknown		Not Reported
Triamcinolone	S			Not Reported
Gammagard	S	Intravenous (not otherwise specified)		Not Reported
Gammagard	S			Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo Prednisone	S	Oral		Not Reported
Apo Prednisone	S	Oral		Not Reported
Apo Prednisone	S	Oral		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Etanercept	S	Subcutaneous	12.5 Mg 1x1 Week	Not Reported

	Etanercept	S	Subcutaneous	Not Reported
	Gamastan	S	Intramuscular	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Unknown	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Unknown	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Not Reported
	Triamcinolone Acetonide	C	Intra-articular	Not Reported
	Triamcinolone Acetonide	C	Unknown	Not Reported
	Triamcinolone Acetonide	C	Oral	Not Reported
	Triamcinolone Acetonide	C	Intra-articular	Not Reported
	Folic Acid	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17557550	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318948		72 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Fibromyalgia; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Plaquenil /00072602/			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17557559	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318949			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Azithromycin			S	Unknown	Pms		Not Reported
	Benadryl /00000402/			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Demerol			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran /00001501/			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Ezetrol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17557584	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200318937		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Muscle Spasms; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Plaquenil /00072602/	S	Oral	Not Reported
Acetaminophen	C	Unknown	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Thiamine Hydrochloride	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17557586	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318928		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Simponi			S	Subcutaneous			Janssen
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17558039	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200318940			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Muscle Spasms; Off Label Use; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Plaquenil /00072602/			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

	Oxycodone Terephthalate	C	Unknown	Not Reported
	Percocet /00446701/	C	Unknown	Not Reported
	Thiamine Hydrochloride	C	Unknown	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Oxycodone Terephthalate	C	Unknown	Not Reported
	Acetaminophen W/Oxycodone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17566305	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200320978			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Enbrel	S	Unknown	Duration- 730 And 731 (Unspecified Units)	Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
Cimzia	S	Unknown		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Vitamin D3	C	Unknown		Not Reported
Imuran /00001501/	C	Unknown		Not Reported
Gold	C	Unknown		Not Reported
Arthrotec	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17566309	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200320884		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not			Janssen

Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity			otherwise specified)	
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo Leflunomide	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil /00072602/	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17575971	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP008932		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported

Enbrel	S	Subcutaneous	25 Mg, Q.O.Wk.	Not Reported
Gold	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
Orencia	S	Subcutaneous	250 Mg, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	25 Unk, Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	200 Mg, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk (1 Every 6 Weeks)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Unk, Cyclical	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Salazopyrin	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Actemra	C	Unknown	Unk	Not Reported
Arava	C	Oral	10 Mg, Unk	Not Reported
Bifidobacterium Bifidum	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Methotrexate	C	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Methotrexate	C	Unknown	20 Mg, Q.Wk.	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	40 Mg, Unk	Not Reported
Prednisone	C	Unknown	250 Mg, Unk	Not Reported

Simponi	C	Unknown	Unk		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Wellbutrin	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17577750	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200320438		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Lyrica			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17580229	EXPEDITED (15-DAY)		DS, OT	CA-BIOVITRUM-2020CA1335		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported

Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Apo-Leflunomide	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous	Dose: 17.5 Mg	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Risedronate	S	Unknown		Not Reported
	Risedronate Sodium	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral		Not Reported
	Risedronate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17596897	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068369		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg Solution		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17596961	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068453			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava			S		Unk		Sanofi
	Prednisone			S		Unk		Not Reported
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Cortisone Acetate			S		Unk		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi

Pseudoephedrine Hydrochloride	S		Unk		Sanofi
Cimzia	S	Subcutaneous	Unk		Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Humira	S		Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S		Unk		Not Reported
Actemra	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17597473	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068824		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Rheumatoid Arthritis; Shoulder Operation; Therapeutic Response Decreased	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Sulfasalazine			S				Not Reported
	Cymbalta			C				Not Reported
	Hydromorphone			C				Not Reported
	Hydromorph Contin			C				Not Reported
	Lyrica			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17597488	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068873		47 YR	Female	CAN

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

Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide	S	Oral	5 Mg		Sanofi
	Hydroxychloroquine Sulfate	S	Unknown	5 Mg		Sanofi
	Methotrexate	S	Unknown	5 Mg		Not Reported
	Cimzia	S	Subcutaneous	200 Mg		Not Reported
	Enbrel	S	Unknown	50 Mg		Not Reported
	Humira	S	Subcutaneous	40 Mg		Not Reported
	Orencia	S	Unknown	750 Mg		Not Reported
	Remicade	S	Unknown			Not Reported
	Xeljanz	S	Oral	5 Mg, Bid		Not Reported
	Prednisone	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17608427	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009050			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hepatitis; Hypersensitivity; Inflammatory Marker Increased; Keratitis; Off Label Use; Skin Reaction; Synovitis; Thyroid Cancer	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Endocervical	Unk		Apotex
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Etanercept			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Aspirin /00002701/			C	Unknown	Unk		Not Reported
	Avapro			C	Unknown	Unk		Not Reported
	Biaxin			C	Unknown	Unk		Not Reported
	Humalog			C	Unknown	Unk		Not Reported
	Insulin			C	Oral	Unk		Not Reported
	Lantus			C	Unknown	Unk		Not Reported

Metformin Hydrochloride	C	Unknown	Unk		Not Reported
Nystatin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17608759	EXPEDITED (15-DAY)		OT	IT-ADVANZ PHARMA-202002001099			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Platelet Count Decreased; Red Blood Cell Count Decreased; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Imiquimod			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17635250	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014082		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S		25 Milligram, Once Daily (Qd)		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution For Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine			S						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17635999	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218958			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17636247	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-PBT-000018			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Contraindicated Product Administered; Death; Foetal Exposure During Pregnancy; Foetal	Tacrolimus			S	Transplacental			Panacea Biotec
	Hydroxychloroquine			S	Transplacental			Not Reported
	Ramipril			S	Transplacental			Not Reported
	Ramipril			S	Transplacental			Not Reported
	Simvastatin			S	Transplacental			Not Reported

Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Pantoprazole	S	Transplacental	Not Reported
	Metamizole Sodium	S	Transplacental	Not Reported
	Nicotine	S	Transplacental	Not Reported
	Aliskiren	S	Transplacental	Not Reported
	Aliskiren	S	Transplacental	Not Reported
	Torasemide	S	Transplacental	Not Reported
	Salbutamol Sulfate	S	Unknown	Not Reported
	Xarelto	S	Transplacental	Not Reported
	Ezetimibe	S	Transplacental	Not Reported
	Prednisolone	S	Transplacental	Not Reported
	Dalteparin Sodium	S	Unknown	Not Reported
	Acetylsalicylic Acid	S	Transplacental	Not Reported
	Acetylsalicylic Acid	S	Transplacental	Not Reported
	Acetylsalicylic Acid	S	Transplacental	Not Reported
	Novaminsulfon	S	Transplacental	Not Reported
	Novaminsulfon	S	Transplacental	Not Reported
	Torasemide	S	Transplacental	Not Reported
	Rituximab	S	Transplacental	Not Reported
	Enoxaparin Sodium	S	Transplacental	Not Reported
	Misoprostol	C	Transplacental	Not Reported
	Ramipril	S	Transplacental	Not Reported
	Enoxaparin Sodium	C	Transplacental	Not Reported
	Advagraf	S	Transplacental	Not Reported
	Advagraf	S	Transplacental	Not Reported
	Advagraf	S	Transplacental	Not Reported
	Mifegyne	C	Transplacental	Not Reported
	Cyclophosphamide	C	Transplacental	Not Reported
	Heparin	S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17636295	EXPEDITED (15-DAY)		LT	NVSC2020US090949			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Near Death Experience	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Benadryl			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17636540	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1219972		54 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neutropenia	Hidroxicloroquina (2143a)			S	Oral	20 Mg		Teva
	Hidroxicloroquina (2143a)			S	Oral	400mg/12h Dia 1 Seguido De 200mg/12h		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17636766	EXPEDITED (15-DAY)		OT	CA-SA-2020SA085603			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Topicort			S	Topical			Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Folic Acid			S	Subcutaneous	1 Mg		Not Reported
	Prednisone			S				Not Reported
	Alendronate Sodium			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17637797	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029039		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Azathioprine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17637833	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1219073		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap	Ciclosporin			S	Unknown			Ivax
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Orencia		S	Unknown		Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported
	Xeljanz		C	Oral	10 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638187	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1219970		58 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mixed Liver Injury	Hidroxicloroquina (2143a)			S	Oral	400mg / 12h Day 1 Followed By 200mg / 12h		Teva
	Hidroxicloroquina (2143a)			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638596	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2020GMK047124			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Nausea; Osteoarthritis; Osteopenia; Pleural	Gabapentin			S	Unknown	100 Milligram, Bid		Glenmark
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram; 1 Every 1 Month		Not Reported
	Arava			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Oxycontin			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2.5 Gram, Qd		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, 1 Every 3		Not Reported

Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure				Week	
	Myochrysine	S	Intramuscular	50 Milligram; 1 Every 3 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qw (1 Every 1 Week)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qw (1 Every 1 Week)	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, 1 Every 1 Month	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid (2 Every 1 Day)	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Qd	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Unk, Od	Not Reported
	Ergocalciferol	C	Unknown	Unk, Od (1 Every 1 Day)	Not Reported
	Ergocalciferol	C	Unknown	400 Iu International Unit(S), Qd	Not Reported
	Esomeprazole	C	Unknown	40 Milligram, Bid (2 Every 1 Day)	Not Reported
	Ferrous Fumarate	C	Unknown	300 Milligram, Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Hydroxocobalamin	C	Unknown	Unk	Not Reported
	Loperamide Hydrochloride	C	Unknown	2.5 Milligram, Unk	Not Reported
	Nasonex	C	Unknown	2 Dosage Form, Bid	Not Reported
	Nicotinamide	C	Unknown	Unk	Not Reported
	Nortriptyline Hydrochloride	C	Oral	40 Milligram, Od	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram, Unk	Not Reported
	Prednisone	C	Unknown	5.0 Gigabecquerel, Od	Not Reported
	Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
	Riboflavin	C	Unknown	Unk	Not Reported

	Risedronate Sodium	C	Unknown	36 Milligram, Qw (1 Every 1 Week)	Not Reported
	Sodium Ascorbate	C	Unknown	Unk	Not Reported
	Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
	Thiamine Mononitrate	C	Unknown	Unk	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Milligram, Od	Not Reported
	Tylenol /00020001/	C	Unknown	1000 Milligram, Qd	Not Reported
	Vitamin A /00056001/	C	Unknown	Unk	Not Reported
	Vitamin C /00008001/	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638618	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1219130			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638636	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1219180		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638655	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218933		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling;	Ciclosporin			S	Unknown			Ivax
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17638683	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218942		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Overlap Syndrome; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin			S	Unknown			Ivax
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17639284	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003002713			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatic	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	Unk		Not Reported

Fibrosis; Therapeutic Response Decreased	Methotrexate		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17639471	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2020-FR-001059			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cardiomyopathy; Cutaneous Lupus Erythematosus; Neutropenia; Renal Failure; Retinal Injury; Thrombocytopenia; Toxicity To Various Agents	Chloroquine Phosphate			S	Unknown	300 Milligram, Qd		Ipca
	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17641570	EXPEDITED (15-DAY)		OT	NVSC2020US094182		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17641778	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-028981			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Piroxicam	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	12736125	NON-EXPEDITED			US-PFIZER INC-2016421350		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Animal Scratch; Impaired Healing; Therapeutic Product Effect Incomplete	Xeljanz			S		5 Mg, Unk		Pfizer
	Xeljanz			S		10 Mg, Unk		Pfizer
	Xeljanz			S		5 Mg, Unk		Pfizer
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported
	Duloxetine			S		30 Mg, Unk		Not Reported
	Vitamin D2			S		50000 Iu, Weekly		Not Reported
	Alendronate			S		70 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	13519393	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038017		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Unknown	750 Mg		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	20 Milligram		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Milligram		Not Reported
	Leflunomide			S	Oral	20 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Meloxicam			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	13676502	EXPEDITED (15-DAY)		OT	CA-TEVA-780631ACC		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension;	Actonel			S	Unknown			Teva
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate Sodium			S	Subcutaneous			Barr
	Methotrexate Sodium			S	Subcutaneous			Barr
	Risedronic Sodium			S	Unknown			Teva

Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Risedronic Sodium	S	Oral		Teva
	Risedronic Sodium	S	Unknown		Teva
	Actemra	S	Unknown		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown	300 Milligram Daily;	Not Reported
	Plaquenil	S	Oral	300 Milligram Daily;	Not Reported
	Plaquenil	S	Oral	300 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	1 Dosage Forms Daily;	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
	Apo-Risedronate	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported

	Hydroxychloroquine	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15621982	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557440-00		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15623808	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555897-00		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Unevaluable	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Minocycline			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported

Event	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Amoxicillin Sodium And Clavulanate Potassium	C	Unknown	Not Reported
	Amoxil	C	Unknown	Not Reported
	Clavulin	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Bcg	C	Intravesical	Not Reported
	Bcg	C	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass	C		Not Reported
	Risedronate	C	Oral	Not Reported
	Amoxicillin And Clavulanate	C	Unknown	Not Reported

	Potassium Adalimumab			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15630623	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556317-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15651514	EXPEDITED (15-DAY)		DS, LT, OT	CA-GLAXOSMITHKLINE-CA2015187246			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Event; Alopecia;	Cetirizine Hydrochloride			S		10 Mg, Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S		Unk		Glaxosmithkline

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride	S	Oral	10 Milligram, Once Daily (Qd)	Glaxosmithkline
	Cetirizine Hydrochloride	S	Oral	10 Milligram	Glaxosmithkline
	Cetirizine Hydrochloride	S		Unk	Glaxosmithkline
	Zyrtec-D	S		10 Mg, Unk	Glaxosmithkline
	Zyrtec-D	S			Glaxosmithkline
	Cirrus	S		Unk	Glaxosmithkline
	Cetirizine Hydrochloride	S	Oral	10 Milligram, Once Daily (Qd)	Glaxosmithkline
	Cetirizine Hydrochloride	S			Glaxosmithkline
	Folic Acid	S		5 Mg, Unk	Glaxosmithkline
	Folic Acid	S		5 Milligram	Glaxosmithkline
	Folic Acid	S		1 Milligram	Glaxosmithkline
	Folic Acid	S		1 Mg	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Desoximetasone	S	Oral	Unk	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S		Unk	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S		1 Milligram	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S		25 Milligram	Glaxosmithkline
	Pseudoephedrine Hydrochloride	S		10 Milligram	Glaxosmithkline
	Diclofenac Sodium	S		Unk	Glaxosmithkline
	Paracetamol	S		Unk	Glaxosmithkline
	Cortisone Acetate	S	Topical	25 Milligram	Glaxosmithkline
	Diclofenac	S		Unk	Glaxosmithkline
	Topicort	S	Cutaneous	Unk	Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S		Controlled Release Tablets	Not Reported
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride	S		25 Milligram, Ointment	Not Reported
	Cimzia	S	Subcutaneous	Dosage Form: Solution	Not Reported
	Cimzia	S			Not Reported
	Fosamax	S	Oral	Unk	Not Reported

Fosamax	S	Oral	Unk	Not Reported
Sulfathalidine	S		Dosage Form: Unspecified	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Oral	20 Milligram	Not Reported
Arava	S	Oral	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Mg, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Sulfasalazine	S		Unk	Not Reported
Apo-Folic Acid	S		5 Mg, Unk	Not Reported
Apo-Hydroxyquine	S		Unk	Not Reported

Apo-Prednisone	S		1 Milligram	Not Reported
Apo-Prednisone	S		5 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Lyophilized Powder	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported
Stelara	S		Unk	Not Reported
Prednisone	S	Oral	Dosage Form: Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Sarilumab	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Glaxosmithkline
Simponi	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg (0.8 Ml)	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Sunconjunctival	40 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported

Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
Plaquenil	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Salazopyrin	C		Unk	Not Reported
Atasol (Acetaminophen)	C		Unk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk Unk, Once Daily (Qd)	Not Reported

Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)		Not Reported
Adalimumab	S		Unk		Not Reported
Golimumab	S		Unk		Not Reported
Leflunomide	S	Oral	Unk		Not Reported
Desoximetasone	S	Oral	Cutaneous Route		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15664903	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2571352-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15712495	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587774-00		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15738004	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2595168-00		62 YR	Female	CAN

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

Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Meloxicam	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	15916855	EXPEDITED (15-DAY)		OT	CA-COLGATE PALMOLIVE COMPANY-20190100275			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State; Contraindicated Product Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect	Periogard Unspecified			S	Unknown	Unk		Colgate
	Chlorhexidine Gluconate Unspecified			S	Unknown	Unk		Colgate
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg, Q4wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg, Q4wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram, Qmo		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Decreased; Therapeutic Product Effect Decreased; Weight Increased	Enbrel	S		Unk	Not Reported
	Enbrel	S		Unk	Not Reported
	Sulfamethoxazole	S	Unknown	Unk	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Unk	Not Reported
	Simponi	S	Periarticular	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S		Unk	Not Reported
	Acetaminophen	S	Unknown	Unk	Not Reported
	Apo Acetaminophen	S	Unknown	Unk	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Oxycodone Terephthalate	S	Unknown	Unk	Not Reported
	Sulfamethoxazole;Trimethoprim	S	Unknown	Unk	Not Reported
	Oxycodone Actavis	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Oxycodone;Paracetamol	S	Unknown		Not Reported
	Oxycodone Hydrochloride;Paracetamol	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown	Unk	Not Reported
	Desogestrel And Ethinyl Estradiol	C	Unknown	Unk	Not Reported
	Desogestrel And Ethinyl	C		Unk	Not Reported

Estradiol				
Arava	C	Oral	20 Milligram, Qd	Not Reported
Arava	C	Unknown	Unk	Not Reported
Prednisone	C	Oral	7.5 Mg, 1x/Day	Not Reported
Prednisone	C	Oral	7.5 Mg, Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Pantoloc [Pantoprazole Sodium Sesquihydrate]	C	Unknown	Unk	Not Reported
Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported
Tylenol [Paracetamol]	C		Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C		400 Mg, 1x/Day	Not Reported
Pantoprazole Sodium	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Cetirizine Dihydrochloride	C	Unknown	Unk	Not Reported
Paracetamol	C	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	C			Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	C		Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C		400 Mg, 1x/Day	Not Reported
Tylenol With Codeine	C	Unknown	Unk	Not Reported
Cetirizine	C	Unknown		Not Reported
Paracetamol Codeine	C	Unknown	Unk	Not Reported
Cetirizine	C	Unknown		Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
Tylenol No.1	C			Not Reported
Hydroxychloroquine Phosphate	C	Unknown		Not Reported

	Zopiclone	C	Unk	Not Reported
	Marvelon 28	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	16575509	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2852070-00		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Diclofenac Sodium/Misoprostol			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychoroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Vitamin D3			C				Not Reported
	Ergocalciferol			C				Not Reported
	Colecalciferol			C				Not Reported
	Imuran			C				Not Reported
	Gold			C				Not Reported
	Arthrotec			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	16864058	EXPEDITED (15-DAY)		OT	DE-GILEAD-2019-0424518			Female	DEU

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

Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ambrisentan	S	Unknown	Unk	Gilead
	Roactemra	S	Unknown	162 Mg, Z(Weekly)	Not Reported
	Quensyl	S	Unknown	20 Mg, Bid	Not Reported
	Ramipril	S	Unknown	2.5 Mg, Bid	Not Reported
	Spasmolyt	S	Unknown	15 Mg, Qd	Not Reported
	Eliquis	S	Unknown	2.5 Mg, Bid	Not Reported
	Eliquis	S	Unknown	1 Dosage Form	Not Reported
	Omeprazole	S	Unknown	20 Mg, Bid	Not Reported
	Lyrica	C	Unknown	100 Mg, Tid	Not Reported
	Pregabalin	S	Unknown	100 Mg, Tid	Not Reported
	Sildenafil Citrate	S	Unknown	60 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	16991114	EXPEDITED (15-DAY)		OT	CA-SA-2019SA303996			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral			Sanofi
	Diclofenac Sodium			S				Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S				Not Reported
	Arava			S	Oral			Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S				Not Reported
	Folic Acid			S		1 Mg		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Intra-arterial	25 Mg		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S				Sanofi

Pseudoephedrine Hydrochloride	S				Sanofi
Sulfasalazine	S		500 Mg		Not Reported
Cimzia	S	Subcutaneous			Not Reported
Actemra	S	Subcutaneous			Not Reported
Cortisone Acetate	S	Topical	25 Mg		Not Reported
Enbrel	S	Subcutaneous			Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Methotrexate Sodium	S				Not Reported
Orencia	S	Intravenous (not otherwise specified)			Not Reported
Orencia	S	Subcutaneous	Unk		Not Reported
Phthalylsulfathiazole	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)			Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Simponi	S				Not Reported
Apo Prednison	S				Not Reported
Xeljanz	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17405411	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-008376		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Lyrica			S	Oral			Not Reported

Methotrexate	S	Unknown	Unk		Not Reported
Mycophenolate Mofetil	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous drip	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17433130	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0820		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Fatigue; Infiltration Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Treatment Failure; Vasculitic Rash	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg (Previously)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg (Previously)		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	1 Every 2 Weeks And 1 Every 1 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1 Every 4 Weeks, 1 Every 4 Months, 1 Every 1 Months		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral	12.5 Mg 1x1 Daily	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous	Dose. 12.5 Mg	Not Reported
	Neoral	S	Oral		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Remicade	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17579771	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327850		27 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17579774	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327867		63 YR	Female	CAN

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

Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Unevaluable Event; Urinary Tract Infection	Simponi	S	Subcutaneous	Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Prednisone	S	Oral	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Celebrex	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Morphine	C	Unknown	Not Reported
	Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17583352	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024371		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Pregabalin			S	Oral	Unk		Not Reported

Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab;Vorhyaluronidase Alfa	S	Subcutaneous	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Lyrica	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Piroxicam	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17584892	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2020125649		65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Pneumonia	Methotrexate Sodium			S		Unk		Pfizer
	Rituximab			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17587303	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329619			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17587307	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327870		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Drug Ineffective; Gastric Ulcer; Gastrointestinal Disorder; Haemoptysis; Peptic Ulcer	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17605637	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333273		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Simponi			S	Subcutaneous			Janssen
	Otezla			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17605638	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333296		51 YR	Female	CAN

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

Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use	Simponi	S	Subcutaneous		Janssen
	Cimzia	S	Subcutaneous	Cimzia Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown	1.0 Dosage Forms	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Arava	C	Oral		Not Reported
	Codeine Phosphate	C	Unknown		Not Reported
	Lyrica	C	Oral		Not Reported
	Tylenol	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17641623	EXPEDITED (15-DAY)		HO, OT	EG-ADVANZ PHARMA-202003002270			Unknown	EGY

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Blindness; Blood Glucose Abnormal; Brain Oedema; Loss Of Consciousness	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia
	Insulin			C		30 Iu, Qd		Not Reported
	Menthol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17642134	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002077			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hip Surgery; Pain	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17642991	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029406		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown	500 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17644154	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1220064		40 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Hidroxicloroquina (2143a)			S	Oral	400 Mg / 12 Day 1 Followed By 200 Mg / 12h		Teva
	Hidroxicloroquina (2143a)			S	Oral			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17644416	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202003002706			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism; Respiratory Failure	Hydroxychloroquine			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine			S		400 Mg, Qd		Concordia
	Morphine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17644417	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202003002359			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17645665	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2020CA1655		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Anakinra			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Oral			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

Leflunomide	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Orencia	S	Subcutaneous		Not Reported
Penicillamine	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Docusate Sodium	C	Oral		Not Reported
Elavil	C	Unknown		Not Reported
Tobramycin	C	Unknown	0.3% 4x1 Daily	Not Reported
Cyclophosphamide	C	Intravenous (not otherwise specified)		Not Reported
Doxycycline	C	Oral		Not Reported
Prednisone	C	Oral		Not Reported
Sulfasalazine	C	Oral	1.5 G 2x1 Daily	Not Reported
Sulfasalazine	C	Unknown		Not Reported
Wellbutrin	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17645724	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009359			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nephrotic Syndrome	Prednisone			S	Oral	Unk		Not Reported
	Mycophenolate			S	Unknown	Unk		Novartis
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

	Imuran /00001501/	S	Unknown	Unk		Not Reported
	Cellcept /01275102/	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17645727	NON-EXPEDITED			NVSC2020US094449		26 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Colchicine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17646286	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202003002360			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17646292	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202003002361			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17646454	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002357			Unknown	FRA

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

Arrhythmia; Off Label Use; Prostatic Adenoma	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil		S	Unknown	1 Dosage Form, Qd (Film-Coated Tablet)	Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17646991	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-028979		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17647436	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3356481-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

	Remicade	S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17648477	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-VALIDUS PHARMACEUTICALS LLC-SK-2020VAL000270			Unknown	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction; No Adverse Event; Oligohydramnios; Premature Baby	Metoprolol Tartrate			S	Transplacental	Unk		Validus
	Cefotaxime Sodium			S	Transplacental	Unk		Validus
	Cefotaxime Sodium			S	Transplacental	Unk		Validus
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Cefixime			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Paracetamol			S	Transplacental	Unk		Not Reported
	Methylprednisolone			S	Transplacental	Unk		Not Reported
	Methylprednisolone			S	Transplacental	Unk		Not Reported
	Omeprazole			S	Unknown	Unk		Not Reported
	Magnesium Lactate			S	Transplacental	Unk		Not Reported
	Calcium Carbonate			S	Transplacental	Unk		Not Reported
	Bisoprolol Fumarate			S	Transplacental	Unk		Not Reported
	Fluconazole			S	Transplacental	Unk		Not Reported
	Hydrocortisone			S	Transplacental	Unk		Not Reported
	Potassium Chloride			S	Transplacental	Unk		Not Reported
	Benzylpenicillin Sodium			S	Transplacental	Unk		Not Reported
	Colecalciferol			S	Transplacental	Unk		Not Reported
	Cefazolin Sodium			S	Transplacental	Unk		Not Reported

	Albumin (Human)	S	Transplacental	Unk		Not Reported
	Vitamin B Complex	S	Unknown	Unk		Not Reported
	Aminomethylbenzoic Acid	S	Transplacental	Unk		Not Reported
	Flebogamma Dif /00025201/	S		Unk		Not Reported
	Privigen	S	Transplacental	Unk		Not Reported
	Privigen	S	Transplacental	Unk		Not Reported
	Bisulepin	S	Transplacental	Unk		Not Reported
	Folic Acid	S	Transplacental	Unk		Not Reported
	Etamsylate	S	Transplacental	Unk		Not Reported
	Nadroparine	S	Transplacental	Unk		Not Reported
	Ornidazole	S	Transplacental	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17648751	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3356478-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17649052	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029653			Female	CAN

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

Drug Ineffective; Rheumatoid Arthritis	Orencia	S	Unknown		Bristol Myers Squibb
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown	25 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17649456	DIRECT	Y	DE			65 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Test Positive	Hydroxychloroquine Sulfate Tablets			S	Oral			Teva
	Oseltamivir Phosphate			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Sodium Chloride 0.9% 1000 Ml			C				Not Reported
	Azithromycin 500 Mg			C				Not Reported
	Zosyn 3.375 G			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Atropine			C				Not Reported
	Epinephrine			C				Not Reported
	Acetaminophen			C				Not Reported
	Ceftriaxone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17649584	NON-EXPEDITED			US-TEVA-2020-US-1213903			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Therapeutic Response Unexpected	Hydroxychloroquine Sulfate			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17649858	NON-EXPEDITED			NVSC2020US093707			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort	Hydroxychloroquine Sulfate			S	Unknown			Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651020	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029403		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

	Sulfasalazine		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651063	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-028965			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651130	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029423		74 YR	Female	CAN

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

Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Sciatica	Orencia	S	Unknown		Bristol Myers Squibb
	Acetaminophen	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown	7 Milligram, Qd	Not Reported
	Apo-Ramipril	S	Unknown	Unk, Qd	Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Levothyroxine	S	Unknown	Unk, Qd	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	400 Milligram, Qd	Not Reported
	Acetaminophen, Caffeine, Dihydrocodeine Bitartrate	C	Unknown		Not Reported
	Acetaminophen;Codeine	C	Unknown		Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate	C	Ophthalmic	Unk, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651159	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029452			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported

Mycophenolate Mofetil	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Lyrica	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Humira	S	Unknown	40 Milligram		Not Reported
Enbrel	S	Unknown			Not Reported
Arava	S	Unknown			Not Reported
Actemra	S	Unknown			Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Piroxicam	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17651582	DIRECT	Y	OT			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported
	Amiodarone			S	Oral			Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	11257960	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-046061		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported

Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Gold	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	1 Ml, Qwk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	7 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Mycophenolic Acid	S	Unknown		Not Reported
	Methotrexate	S	Unknown	1 Milliliter	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Cellcept [Mycophenolate Mofetil]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Xeljanz	C	Oral	5.0 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	12913793	EXPEDITED (15-DAY)		DS, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Paracetamol			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram, Qd		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Oral	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Cortisone Acetate			S	Oral	25 Milligram		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported

Failure; Wound	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Sunconjunctival	Unk	Not Reported
	Humira	S	Sunconjunctival	40 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	1 Gram, Bid	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	Unk, Qd	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram, Qd	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravesical	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported

Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Xeljanz	S	Unknown	5 Milligram, Q12h	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Zyrtec [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	25 Milligram	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	1 Milligram	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	25 Milligram	Not Reported
Kevzara	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride And	S	Unknown	25 Milligram	Not Reported

Pseudoephedrine Hydrochloride				
Etanercept	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Golimumab	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Oral	10 Milligram	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Prednisone	S	Unknown	5 Unk	Not Reported
Prednisone	S	Unknown	1 Milligram	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Acetaminophen	S	Unknown	Unk	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Oral	25 Milligram	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported

Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	25 Milligram	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Oral	Unk Unk, Bid	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	1 Milligram	Not Reported
Folic Acid	S	Oral	25 Milligram	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Cortisone	S	Unknown	25 Milligram	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Winpred	S	Oral	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Zyrtec-D	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Lisinopril	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	50 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	13064952	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20161217720			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Drug Ineffective; Joint Injury; Knee Arthroplasty; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Urticaria	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Pertussis Vaccine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	13659278	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170611422		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported

Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Cellcept	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Mycophenolate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Pregabalin	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Piroxicam	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	14501669	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007157		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Apo-Folic Acid			S	Unknown	5 Milligram, 2 Times/Wk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram		Not Reported

Liver Injury; Fall; Fatigue; Femur Fracture; Haematocrit Decreased; Haemoglobin Decreased; Impaired Healing; Joint Swelling; Multiple Fractures; Musculoskeletal Pain; Off Label Use; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Co Atenolol	S	Unknown	25 Milligram, Qd	Not Reported
	Co Atenolol	S	Unknown	20 Milligram, Qd	Not Reported
	Atenolol	S	Unknown	25 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Q2wk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Q2wk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Qwk	Not Reported
	Naprosyne	S	Oral	1000 Milligram, Qd	Not Reported
	Naprosyne	S	Oral	100 Milligram, Qd	Not Reported
	Naprosyne	S	Oral	500 Milligram, Bid	Not Reported
	Palafer Cf	S	Unknown	1 Dosage Form, 1 Every 24 Hrs	Not Reported
	Pantoloc [Pantoprazole Sodium Sesquihydrate]	S	Unknown	40 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	40 Milligram	Not Reported

Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Ascorbic Acid	S	Unknown	Unk Unk, Qd	Not Reported
Actemra	S	Unknown		Not Reported
Naproxen Sodium	S	Oral	500 Milligram, Bid	Not Reported
Naproxen Sodium	S	Unknown	100 Milligram, Qd	Not Reported
Naproxen Sodium	S	Unknown	1000 Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Ferrous Fumarate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	25 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	20 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	20 Milligram, Cyclical	Not Reported
Naproxen	S	Oral	500 Milligram, Bid	Not Reported
Naproxen	S	Oral	100 Milligram, Qd	Not Reported
Naproxen	S	Oral	1000 Milligram, Qd	Not Reported
Celecoxib	S	Unknown		Not Reported
Folic Acid	S	Unknown	5 Milligram, Q2wk	Not Reported
Folic Acid	S	Unknown	5 Milligram, Bid	Not Reported
Folic Acid	S	Unknown	400 Milligram	Not Reported
Folic Acid	S	Unknown	5 Unk	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Qwk	Not Reported
Hydroxychloroquine	S	Unknown	40 Unk	Not Reported
Ferrous Fumarate;Folic Acid	S	Unknown	Unk Unk, Qd	Not Reported
Xeljanz	S	Unknown		Not Reported
Pantoprazole	S	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown	40 Milligram, Qd	Not Reported
Methotrexate	S	Oral	20 Milligram, Q2wk	Not Reported

Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
Naprosyn [Naproxen Sodium]	S	Oral	1000 Milligram, Qd	Not Reported
Naprosyn [Naproxen Sodium]	S	Oral	500 Milligram, Bid	Not Reported
Naprosyn [Naproxen Sodium]	S	Oral	100 Milligram, Qd	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Palafer	S	Unknown	Unk	Not Reported
Teva Pantoprazole	S	Unknown	40 Milligram, Qd	Not Reported
Vitamin C [Ascorbic Acid]	S	Unknown	Unk, Qd	Not Reported
Pantoprazole Sodium	S	Unknown	40 Milligram, Qd	Not Reported
Celebrex	C	Oral	200 Milligram, Qd	Not Reported
Celecoxib	C	Oral	200 Milligram, Qd	Not Reported
Prednisone	C	Intracardiac	5 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	14535482	EXPEDITED (15-DAY)		DS, OT	CA-BIOVITRUM-2018CA0123			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Arthralgia; Arthropathy; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Foot Deformity; Foot Operation; Hepatotoxicity; Ill-Defined Disorder; Infection; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Nausea; Neck Pain;	Kineret			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S		400,0 Milligram		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not	Powder For Solution		Not Reported

Nodule; Off Label Use; Pain; Rheumatoid Arthritis; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete			otherwise specified)	Intravenous	
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Gold	S			Not Reported
	Plaquenil	S			Not Reported
	Plaquenil	S	Oral	400mg	Not Reported
	Apo-Hydroxyquine	S			Not Reported
	Methotrexate	S		Dose: 17.5 Mg	Not Reported
	Methotrexate	S			Not Reported
	Actonel	S			Not Reported
	Apo-Leflunomide	S			Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Codeine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Adalimumab	C	Unknown		Not Reported
	Xeljanz	C			Not Reported
	Methotrexate	C		Dosage Form: Not Specified	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	14750177	EXPEDITED (15-DAY)		DE, OT	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-031026		67 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contusion; Death; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction	Warfarin Sodium			S	Unknown	Unk		Bristol Myers Squibb
	Aspirin			S	Unknown	Unk		Bristol Myers Squibb
	Influenza Vaccine			S	Unknown	Unk		Not Reported

Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Celecoxib	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Montelukast	S	Unknown	Unk		Not Reported
	Hydrochlorothiazide	S	Unknown	Unk		Not Reported
	Lorazepam	S	Unknown	Unk		Not Reported
	Asa	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15065924	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0717		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Operation; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Kineret			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported

Leflunomide	S			Not Reported
Leflunomide	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Rituximab	S			Not Reported
Bupropion	C	Oral		Not Reported
Sulfasalazine	C			Not Reported
Wellbutrin	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15219753	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-NODEN PHARMA DAC-NOD-2018-000052			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Rasilez			S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week		Noden Pharma
	Rasilez			S				Noden Pharma
	Prednisolone			S	Transplacental	From Gestational Week 0-14		Not Reported
	Prednisolone			S	Transplacental	Unk		Not Reported
	Salbutamol Sulfate			S	Transplacental	Unk, If Required; Trimester: First+Second;From Gestational Week 0-14		Not Reported
	Salbutamol Sulfate			S	Transplacental	Unk		Not Reported
	Delix /00885601/			S	Transplacental	Maternal Dose 20 Mg, Qd (Exposure Duration 0-13+6 Weeks)		Not Reported
	Delix /00885601/			S				Not Reported
	Quensyl			S	Transplacental	400 [Mg/D (2x200)]; 0-13.6 Gestational Week;From Gestational Week 0-14		Not Reported
	Quensyl			S	Transplacental	Unk		Not Reported

Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid	S			Not Reported
Pantozol /01263204/	S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week;From Gestational Week 0-14 (Busco Pantoprazole)	Not Reported
Pantozol /01263204/	S	Transplacental	Unk	Not Reported
Torasemide	S	Transplacental	From Gestational Week 0-14	Not Reported
Torasemide	S	Transplacental	Unk	Not Reported
Advagraf	S	Transplacental	6 [Mg/D]; 0-13.6 Gestational Week, From Gestational Week 0-14	Not Reported
Advagraf	S	Transplacental	Unk	Not Reported
Advagraf	S			Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Nicotine	S	Transplacental	Unk	Not Reported
Ezetimibe Msd	S	Transplacental	From Gestational Week 0-14	Not Reported
Novaminsulfon	S	Transplacental	Exposure Duration: 0-14 Weeks. Trimester: First; Probably Only In Hospital In Week 5.	Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Novaminsulfon	S	Transplacental	300 Milligram, Qd	Not Reported
Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported

Clexane	S	Transplacental	200 Milligram, Qd		Not Reported
Clexane	S	Transplacental	200 Mg/D (2x100)		Not Reported
Clexane	S				Not Reported
Heparin Lmw	S	Transplacental	Unknown		Not Reported
Heparin Lmw	S				Not Reported
Enoxaparin	S	Transplacental	From Gestational Week 0-14		Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional		Not Reported
Rituximab	S	Transplacental	Unk		Not Reported
Heparin	S	Transplacental	Unk (Low Molecular Weight Heparin)		Not Reported
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week		Not Reported
Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week		Not Reported
Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional		Not Reported
Cyclophosphamide	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15320710	EXPEDITED (15-DAY)		CA, DE, DS, OT	PHHY2018DE077729			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Aliskiren			S	Transplacental	Unk		Not Reported
	Ezetimibe			S	Transplacental	Unk		Novartis
	Prednisolone			S	Transplacental	Unk		Not Reported
	Salbutamol			S	Transplacental	Unk		Not Reported
	Torasemide			S	Transplacental	Unk		Not Reported
	Ramipril			S	Transplacental	Maternal Dose: 20mg		Not Reported
	Simvastatin			S	Transplacental	Unk		Not Reported

Tacrolimus	S	Transplacental	Unk	Not Reported
Pantoprazol	S	Transplacental	Unk	Not Reported
Metamizole	S	Transplacental	(Maternal Dose: 300mg, Qd)	Not Reported
Acetylsalicylic Acid	S	Transplacental	Unk	Not Reported
Xarelto	S	Transplacental	Unk	Not Reported
Hydroxychloroquine	S	Transplacental	Unk	Not Reported
Enoxaparin	S	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15551940	EXPEDITED (15-DAY)		CA	DE-TEVA-2018-DE-967934			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S	Transplacental			Actavis
	Torem			S	Transplacental	100 [Mg/D]		Not Reported
	Quensyl			S	Transplacental	200 Milligram Daily; Daily Dose: 400 Mg Millgram(S) Every Days		Not Reported
	Rituximab			S	Transplacental	Last Time In December 2011: Pre Or Periconceptional		Not Reported
	Inegy			S	Transplacental	40 [Mg/D] / 10 [Mg/D]		Not Reported
	Delix (Ramipril)			S	Transplacental	20 [Mg/D]		Not Reported
	Advagraf			S	Transplacental	6 [Mg/D]		Not Reported
	Pantozol			C	Transplacental	40 [Mg/D]		Not Reported
	Albuterol			C	Transplacental	Unk, Prn		Not Reported
	Cytotec			C	Transplacental	Unk		Not Reported
	Cyclophosphamid			C	Transplacental	3000 [Mg Cumulative]/ April -August 2011		Not Reported
	Xarelto 10 Mg Filmtabletten			C	Transplacental	Not Known, If Treatment Started Before Or After Missed Abortion.		Not Reported

	Clexane	C	Transplacental	200 [Mg/D (2x100)]	Not Reported
	Novaminsulfon	C	Unknown	For 5 Weeks	Not Reported
	Aliskiren	C	Transplacental	300 [Mg/D]	Not Reported
	Mifegyne	C	Transplacental	Unk	Not Reported
	Rasilez	C	Transplacental	300 [Mg/D]	Not Reported
	Salbutamol	C	Transplacental	If Required	Not Reported
	Prednisolon	C	Transplacental	Daily Dose: 10 Mg Milligram(S) Every 2 Day	Not Reported
	Ass	C	Transplacental	100 [Mg/D]	Not Reported
	Novaminsulfon	C	Transplacental	Probably Only In Hospital In Week 5	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15623961	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557378-00		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Multiple Allergies; Multiple Allergies; Musculoskeletal Pain; Musculoskeletal Pain; Off Label Use; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Incomplete; Treatment Failure; Unevaluable Event	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Mycophenolate Mofetil Hydrochloride	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo Mycophenolate	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Sodium Aurothiomalate	S	Oral	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Cyclosporine	S	Oral	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Piroxicam	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Pregabalin	S	Oral	Not Reported
	Teva Mycophenolate	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Piroxicam	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15635156	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105525		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Gram, Q2wk		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	2000 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	Unk Unk, Q2wk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	15957810	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190213510			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17533403	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200243621		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Crohn'S Disease; Drug Hypersensitivity; Drug Ineffective; Lower Respiratory Tract Infection; Nasopharyngitis; Off Label Use; Product Use In Unapproved Indication	Stelara			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Gabapentin			S	Unknown			Not Reported
	Perindopril			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cosentyx			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17558247	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200316516		60 YR	Female	CAN

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

Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Simponi	S	Subcutaneous	Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported
	Methotrexate Sodium	C	Oral	Not Reported
	Prednisone	C		Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17577764	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329945			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

			otherwise specified)	
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Hydroxychloroquine	C		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17577767	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329960			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sarilumab			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Methotrexate	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Rabeprazole Sodium	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17605627	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332798			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17605641	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333272		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Off Label Use;	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not			Janssen

Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased			otherwise specified)		
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Adalimumab	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Cimzia Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Celebrex	C	Unknown		Not Reported
	Diclofenac	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Oral		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Tocilizumab	C	Endocervical		Not Reported
	Valsartan	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17605642	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332799		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1.0 Dosage Forms		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17605650	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332795		38 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden; Crying; Drug Ineffective	Simponi			S	Subcutaneous			Janssen
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Enbrel	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Ergocalciferol	C			Not Reported
Folinic Acid	C			Not Reported
Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17605716	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332774			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17611318	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160614521			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not otherwise specified)	Ndc: 412545		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17623404	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342106		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid	Simponi			S	Subcutaneous			Janssen

Arthritis; Therapeutic Product Effect Decreased	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisolone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17623464	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340472		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use	Simponi			S	Subcutaneous			Janssen
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17633457	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2020CA1653		45 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Contraindicated Product Administered;	Anakinra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Apo-Leflunomide	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Cellcept	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17647143	EXPEDITED (15-DAY)		HO, LT, OT	MX-ALKEM LABORATORIES LIMITED-MX-ALKEM-		29 YR	Female	MEX

2020-01066

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Abscess; Endophthalmitis; Liver Abscess; Muscle Abscess; Myositis; Nocardiosis; Perinephric Abscess; Pneumonia; Pyomyositis	Mycophenolate Mofetil			S	Oral	2.5 Gram, Qd		Alkem
	Hydroxychloroquine			S	Oral	200 Milligram, Qd		Not Reported
	Prednisone			S	Oral	30 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17648078	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029659		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk Unk, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Parenteral	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported

Azathioprine	C	Unknown	Unk, Qd		Not Reported
Ciclosporin	C	Unknown	Unk		Not Reported
Minocycline	C	Unknown	Unk		Not Reported
Penicillamine	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17648606	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029670		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qh		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	175 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate Sodium			S	Unknown	35 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Milligram		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Risedronate			C	Unknown			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17648737	EXPEDITED (15-DAY)		OT	DE-GLAXOSMITHKLINE-DE2020061233		42 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatitis; Erythema Nodosum; Herpes Dermatitis; Herpes Simplex; Immune Reconstitution Inflammatory Syndrome; Immune Reconstitution Inflammatory Syndrome; Lymphoedema; Mass; Nodule; Panniculitis; Papilloma Viral Infection; Periorbital Oedema; Periorbital Swelling	Ceftriaxone Sodium			S	Unknown	Unk		Glaxosmithkline
	Streptomycin			S	Unknown	Unk		Glaxosmithkline
	Cotrimoxazole			S	Unknown	Unk		Glaxosmithkline
	Sulfamethoxazole + Trimethoprim			S	Unknown	Unk		Glaxosmithkline
	Sulfamethoxazole + Trimethoprim			S	Unknown	960 Mg, Qd		Glaxosmithkline
	Ceftriaxone			S	Unknown	Unk		Glaxosmithkline
	Azathioprine			S	Unknown	Unk		Glaxosmithkline
	Acyclovir			S	Unknown	Every 4 Hours.		Glaxosmithkline
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Dose Increased		Not Reported
	Prednisone			S	Unknown	Dose Reduced		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17648841	EXPEDITED (15-DAY)		HO	US-ADVANZ PHARMA-202003002755			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Malaise; Off Label Use	Hydroxychloroquine			S	Unknown			Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17649603	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1219671		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Gabapentin			S	Oral			Actavis
	Fentanyl			S	Unknown			Cephalon
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2.5 Gram Daily;		Not Reported
	Acetaminophen			C				Not Reported
	Aclasta			C				Not Reported
	Docosahexaenoic Acid/Eicosapentaenoic Acid			C				Not Reported
	Nasonex			C				Not Reported
	Prednisone			C				Not Reported
	Trazodone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17651306	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029788			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

Enbrel	S	Unknown	25 Milligram		Not Reported
Humira	S	Subcutaneous	40 Milligram		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd		Not Reported
Methotrexate	S	Unknown	20 Milligram, Qwk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported
Bupropion	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652023	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020146043			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Off Label Use; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Renal Impairment	Methotrexate Sodium			S	Oral			Pfizer
	Methotrexate Sodium			S	Subcutaneous			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652025	EXPEDITED (15-DAY)		OT	RO-ADVANZ PHARMA-202003002774			Unknown	ROM

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Feeling Abnormal; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652040	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004002411			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Eosinophilic Myocarditis; Exposure During Pregnancy; Rash	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652041	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201909000624			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy; Depression; Drug Ineffective; Drug Intolerance; Hypersensitivity; Myelopathy; Neuropathy Peripheral	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Pyridoxine Hydrochloride			S	Unknown	Unk		Not Reported
	Lasix			C		Unk		Not Reported
	Xarelto			C		Unk		Not Reported
	Vitamin B12 Nos			C		Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Bisoprolol			C		Unk		Not Reported
	Fish Oil			C		Unk		Not Reported
	Magnesium			C		Unk		Not Reported
	Ramipril			C		Unk		Not Reported
	Buprenorphine			C		Unk		Not Reported
	Vitamin D			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Vitamin B6			C		Unk		Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652062	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1220063		83 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Skin Lesion; Treatment Failure	Gabapentin			S	Unknown	200 Milligram Daily;		Actavis
	Fentanyl			S	Unknown			Cephalon
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Intravenous (not otherwise specified)	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2.5 Gram Daily;		Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Ascorbic Acid			C	Unknown			Not Reported
	Biotin			C				Not Reported
	D-Alpha Tocopherol			C	Unknown	2400 Milligram Daily;		Not Reported
	Diphenoxylate Hydrochloride			C	Unknown	2.5 Milligram Daily;		Not Reported
	Diphenoxylate Hydrochloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown	400 Iu (International Unit) Daily;		Not Reported
	Esomeprazole			C	Unknown	80 Milligram Daily;		Not Reported

Ferrous Fumarate	C	Unknown			Not Reported
Folic Acid	C				Not Reported
Hydroxocobalamin	C				Not Reported
Loperamide Hydrochloride	C	Unknown			Not Reported
Nasonex	C	Unknown	4 Dosage Forms Daily;		Not Reported
Nicotinamide	C				Not Reported
Nortriptyline Hydrochloride	C	Oral	40 Milligram Daily;		Not Reported
Nortriptyline Hydrochloride	C	Oral			Not Reported
Prednisone	C	Unknown	5 Gbq Daily;		Not Reported
Pyridoxine Hydrochloride	C				Not Reported
Riboflavin	C				Not Reported
Risedronate Sodium	C	Unknown			Not Reported
Sodium Ascorbate	C				Not Reported
Thiamine Hydrochloride	C				Not Reported
Thiamine Mononitrate	C				Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram Daily;		Not Reported
Tylenol	C	Unknown	1000 Milligram Daily;		Not Reported
Vitamin A	C				Not Reported
Vitamin C [Ascorbic Acid]	C				Not Reported
Vitamin D3	C				Not Reported
Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17652287	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1036031		75 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haematochezia	Furosemide			S		Unk		Not Reported
	Dabigatran Etexilate			S	Oral	300 Milligram, Qd		Mylan
	Daparox /00830803/			S		Unk		Mylan
	Lamictal			S		Unk		Mylan
	Plaquenil /00072602/			S		Unk		Mylan
	Valium			S		Unk		Mylan
	Sotalol			S		Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2020	17654933	DIRECT	Y	DE			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Endotracheal Intubation Complication	Hydroxychloroquine			S	Oral			Teva
	Hydroxychloroquine			S	Oral			Teva
	Azithromycin			C				Not Reported
	Albuterol			C				Not Reported
	Lasix			C				Not Reported
	Zosyn			C				Not Reported
	Humulin R			C				Not Reported
	Vancomycin			C				Not Reported
	Lovenox			C				Not Reported
	Tamiflu			C				Not Reported
	Rocephin			C				Not Reported
	Acetaminophen			C				Not Reported
	Zofran			C				Not Reported
	Ns			C				Not Reported
	D50w			C				Not Reported
	Pravachol			C				Not Reported
	Ativan			C				Not Reported
	Doxycycline			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	14535557	EXPEDITED (15-DAY)		CA, OT	CA-BIOVITRUM-2018CA0126			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Incorrect Route Of Product Administration; Insomnia;	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown	2 Every 1 Weeks 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Naprosyn	S	Oral	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Naprosyn	S	Oral	Not Reported
	Orencia	S	Endocervical	Not Reported
	Rituximab	S	Unknown	Not Reported
	Vioxx	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	15635730	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1478917-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	3 Years		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

Hydroxychloroquine	S	Subcutaneous	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	16946977	EXPEDITED (15-DAY)		LT, OT	CA-GLAXOSMITHKLINE-CA2019AMR190534		40 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Fatigue; Off Label Use; Suicidal Ideation	Benlysta			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		200 Mg		Glaxosmithkline
	Benlysta			S	Subcutaneous	Unk		Glaxosmithkline
	Imuran			S	Oral	200 Mg, Qd		Glaxosmithkline
	Plaquenil			S		400 Mg, Qd		Not Reported
	Prednisone			S		20 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17395563	NON-EXPEDITED			US-AMGEN-USASP2020020542		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17433728	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019025070			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Sildenafil			S	Unknown	60 Milligram, Qd		Macleods
	Omeprazole 20 Mg			S	Oral	1 Dosage Form, Bid (1-0-1)		Not Reported
	Omeprazole 20 Mg			S	Oral	20 Milligram, Bid		Not Reported
	Ramipril			S	Oral	1 Dosage Form, Bid (1-0-1) (1 In 12 Hr)		Not Reported
	Ramipril			S	Oral	2.5 Milligram		Not Reported
	Ramipril			S	Unknown	5 Milligram, Qd		Not Reported
	Pregabalin			S	Unknown	1 Dosage Form, Tid (1 - 1-1)		Macleods
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Q.W. (Solution For Injection In Pre-Filled Syringe)		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Q.W. (Solution For Injection In Pre-Filled Syringe)		Not Reported
	Quensyl			S	Unknown	1 Dosage Form, Bid (1-0-0)		Not Reported
	Quensyl			S	Unknown	20 Milligram, Bid		Not Reported
	Quensyl			S	Unknown	80 Milligram, Bid (1 - 0 - 1), 1 Df, Bid		Not Reported
	Eliquis			S	Unknown	1 Dosage Form, Bid (1-0-1)		Not Reported
	Eliquis			S	Unknown	2 Dosage Form, Qd		Not Reported
	Eliquis			S	Unknown	2.5 Milligram, Bid		Not Reported

	Spasmolyt	S	Unknown	1 Dosage Form, Bid ((1-0-1))	Not Reported
	Spasmolyt	S	Unknown	30 Milligram, Qd (0 -0 -1)	Not Reported
	Spasmolyt	S	Unknown	1 Dosage Form, Qd	Not Reported
	Spasmolyt	S	Unknown	15 Milligram, Qd	Not Reported
	Ambrisentan	S	Unknown	30 Milligram, Qd	Not Reported
	Ambrisentan	S	Unknown	Unk	Not Reported
	Lyrica	S	Unknown	100 Milligram, Tid	Not Reported
	Tocilizumab	S	Subcutaneous	162 Milligram, Q.W., Solution For Injection In Pre-Filled Syringe	Not Reported
	Tocilizumab	S	Subcutaneous	162 Milligram, Q.W., Solution For Injection In Pre-Filled Syringe	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17653559	NON-EXPEDITED		OT	US-SA-2020SA089843			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Arava			S				Sanofi
	Plaquenil			S				Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17653880	EXPEDITED (15-DAY)		DE	FR-TEVA-2020-FR-1221561		70 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest	Ebilfumin 75 Mg, Gélule			S	Oral	75 Mg		Teva
	Ceftriaxone Mylan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Plaquenil			S	Oral	At D1 Then 400mg / Day, Unit Dose: 800 Mg		Not Reported
	Coversyl 5 Mg, Comprimé Pelliculé Sécable			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17653955	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-017958		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Levofloxacin			S	Unknown	Unk		Aurobindo
	Lopinavir;Ritonavir			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Once A Day		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	40 Milligram, Once A Day		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	20 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654444	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-017303		76 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Abnormal; Breast Cancer Metastatic; Burning Sensation; Constipation; Dementia Alzheimer'S Type; Expired Product Administered; Gait Disturbance; Intentional Product Misuse; Malaise; Off Label Use; Paronychia; Skin Plaque; Systemic Lupus Erythematosus; Toe Amputation	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S				Aurobindo
	Amoxicillin+Clavulanic Acid			S				Aurobindo
	Plaquenil			S	Unknown	3 Dosage Form		Not Reported
	Plaquenil			S	Unknown	2 Dosage Form, Two Times A Day (One In Morning And One In Evening)		Not Reported
	Plaquenil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654641	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030070		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654647	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029994			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)			Not Reported

	Desoximetasone	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Diclofenac	C	Oral	100 Milligram	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654650	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030021		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	5 Milligram		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Milligram, 2 Every 1 Day		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654666	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1221569			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycine Dihydratee			S	Oral	500 Mg		Not Reported
	Plaquenil 200 Mg, Comprime Enrobe			S	Oral	600 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654748	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3357368-00		39 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hepatocellular Injury	Kaletra 200/50			S	Oral	2 Comp/12h		Not Reported
	Kaletra 200/50			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2gr/24h		Not Reported
	Ceftriaxona			S				Not Reported
	Hidroxicloroquina			S	Oral	200mg/12h		Not Reported
	Hidroxicloroquina			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17654834	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020146015			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Methotrexate Sodium			S	Unknown			Pfizer
	Celebrex			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Xeljanz			S	Unknown			Pfizer
	Codeine Phosphate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17655309	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002613			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Fatigue; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Triatec			C				Not Reported
	Doliprane			C				Not Reported
	Levothyrox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17655685	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1219067		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Unknown			Ivax
	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Actavis
	Ibuprofen			S	Oral	600 Milligram Daily;		Actavis
	Ibuprofen			S	Oral			Actavis
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown	120 Milligram Daily;		Not Reported
	Apremilast			S				Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported

	Hydroxychloroquine	S	Unknown		Not Reported
	Infliximab	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Otezla	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Endocervical		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Benadryl	C			Not Reported
	Colchicine	C	Oral		Not Reported
	Dexilant	C			Not Reported
	Febuxostat	C			Not Reported
	Folic Acid	C			Not Reported
	Gravol	C			Not Reported
	Mogadon	C	Oral		Not Reported
	Nitrazepam	C	Unknown		Not Reported
	Oxycodone	C			Not Reported
	Prednisone	C			Not Reported
	Uloric	C	Unknown	160 Milligram Daily;	Not Reported
	Xeljanz	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17655811	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1220302		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood	Amlodipine Besilate			S	Oral	5 Milligram Daily;		Teva

Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Amlodipine Besilate	S	Oral		Teva
	Gliclazide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Asacol	S	Unknown	2400 Milligram Daily;	Not Reported
	Diamicron	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Atacand Plus	C			Not Reported
	Bisoprolol Fumarate	C			Not Reported
	Diphenhydramine	C	Oral		Not Reported
	Ferrous Gluconate	C			Not Reported
	Folic Acid	C			Not Reported
	Methylprednisolone Acetate	C	Intravenous (not otherwise specified)		Not Reported
	Methylprednisolone Acetate	C	Intra-articular		Not Reported
	Rosuvastatin Calcium	C			Not Reported
	Tylenol	C			Not Reported
	Vitamin D3	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17655893	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202003002355			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence	Hydroxychloroquine			S	Unknown	(Strength: 400mg 2x15 Cprrev		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17656013	EXPEDITED (15-DAY)		OT	GR-PBT-000004		68 YR	Unknown	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dermatomyositis; Disease Progression; Drug Ineffective; Product Use In Unapproved Indication; Vasculitic Rash	Tacrolimus			S	Unknown			Panacea Biotec
	Tacrolimus			S	Unknown			Panacea Biotec
	Thiamazole			C	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Intraocular	200mg Oculus Dexter (Od)		Not Reported
	Hydroxychloroquine			S	Intraocular	200mg Oculus Dexter (Od)		Not Reported
	Hydroxychloroquine			S	Unknown	Dose Was Doubled		Not Reported
	Hydroxychloroquine			S	Unknown	Dose Was Doubled		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse (1 Gr).		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse (1 Gr).		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Two Monthly Intravenous Pulses		Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown	Two Weeks Apart		Not Reported
	Rituximab			S	Unknown	Two Weeks Apart		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17656614	DIRECT	Y	OT			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17656633	DIRECT		OT			50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Dyspnoea	Hydroxychloroquine	Y		S	Oral	Quantity:10 Tablet(S);		Not Reported
	Breo			C				Not Reported
	Dupixent			C				Not Reported
	Green Tea			C				Not Reported
	Magnesium			C				Not Reported
	Black Seed Oil			C				Not Reported
	Blessed Thistle			C				Not Reported
	Sunflower Lecithin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17657153	EXPEDITED (15-DAY)		OT	PL-AMNEAL PHARMACEUTICALS-2020-AMRX-01107		54 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2x/Day		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17657180	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1220398		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug	Amlodipine Besilate			S	Oral	5 Milligram Daily;		Teva
	Gliclazide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Enbrel			S	Subcutaneous			Not Reported

Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Asacol Also Known As Mesalamine	S	Unknown	2400 Milligram Daily;	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Diamicron	S	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Diphenhydramine	C	Oral		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Atacand Plus	C	Unknown		Not Reported
	Bisoprolol Fumarate	C	Unknown		Not Reported
	Depo-Medrol	C	Intra-articular		Not Reported
	Ebastine	C	Unknown		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2020	17657558	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1220718			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Ramipril			S	Oral			Actavis
	Ramipril			S	Unknown			Actavis
	Acetaminophen			S	Unknown			Not Reported
	Dorzolamide/Timolol			S	Unknown	2 Dosage Forms Daily;		Actavis

	Dorzolamide/Timolol	S	Unknown		Actavis
	Prednisone	S	Unknown		Actavis
	Methotrexate	S	Unknown		Barr
	Actemra	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Levothyroxine	S	Unknown		Not Reported
	Levothyroxine	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	15401123	EXPEDITED (15-DAY)		OT	DE-ABBVIE-18K-062-2483634-00		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

Neoral	S	Oral		Not Reported
Neoral	S	Oral		Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Apo-Leflunomide	S	Oral	Tablet	Not Reported
Apo-Leflunomide	S	Oral	Tablet	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous Rituxan	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Methotrexat	S	Subcutaneous	20mg	Not Reported
Methotrexat	S	Oral	20mg, Solution For Injection/Infusion	Not Reported
Methotrexate Sodium	S	Oral	20 Mg	Not Reported
Methotrexate Sodium	S	Subcutaneous	20mg	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw Txt	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw Txt	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg Powder For Solution Intravenous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg Powder For Solution Intravenous	Not Reported
Leflunomide	S	Unknown	Film Coated Tablet	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous		Not Reported
Xeljanz	C	Unknown	2 Ot, Qd	Not Reported
Xeljanz	C	Oral	10 Mg, Qd (5 Mg, Bid)	Not Reported

Xeljanz	C	Oral	2 Ot, Qd		Not Reported
Xeljanz	C	Unknown	2 Ot, Qd		Not Reported
Xeljanz	C	Oral	10 Mg, Qd (5 Mg, Bid)		Not Reported
Xeljanz	C	Oral	2 Ot, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	15621780	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2557337-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthrodesis; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hospitalisation; Infection; Limb Discomfort; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cefazolin			S	Intramuscular			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Viread			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Arava			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	16079912	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06123		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Urticaria	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Humira			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Plaquenil			S	Oral	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Subcutaneous	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown, Solution		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

Sulfasalazine	S	Unknown	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown		Not Reported
Abatacept	S	Unknown	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Rituximab	S	Subcutaneous	Unknown		Not Reported
Certolizumab Pegol	S	Subcutaneous	Unknown		Not Reported
Leflunomide	S	Oral	Unknown		Not Reported
Actemra	C	Unknown	Unknown		Not Reported
Azathioprine	C	Unknown	Unknown		Not Reported
Ciclosporin	C	Unknown	Unknown		Not Reported
Minocycline	C	Unknown	Unknown		Not Reported
Penicillamine	C	Unknown	Unknown		Not Reported
Prednisone	C	Unknown			Not Reported
Tocilizumab	C	Unknown	Unknown		Not Reported
D-Penicillamine	C	Unknown	Unknown		Not Reported
Prednisolone	C	Unknown			Not Reported
Cyclosporin	C	Unknown	Unknown		Not Reported
Phenylbutazone	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658279	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-01638		31 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658282	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-01639		42 YR	Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658365	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2762682-00		47 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Drug Ineffective; Gout; Loss Of Personal Independence In Daily Activities; Metabolic Disorder; Metabolic Surgery; Middle Insomnia; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Product Use Issue; Synovitis; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Allopurinol			C				Not Reported
	Pantoloc			C	Unknown			Not Reported
	Zyloprim			C				Not Reported
	Clomipramine			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658388	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014951			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Leflunomide			S		20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

Hydroxychloroquine Sulfate	S		200 Milligram		Not Reported
Methotrexate	S		20 Milligram		Not Reported
Orencia	S		Unk		Not Reported
Sulfasalazine	S		1 Gram		Not Reported
Xeljanz	C	Oral	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Apr-2020	17658450	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030120			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasis; Tooth Loss	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown	100 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milliliter, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	12776517	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076645		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	14778692	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009922			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Drug Ineffective; Hepatitis; Therapeutic Response Decreased	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

Methotrexate	C	Unknown	20 Mg, Q.Wk.		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15624165	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556702-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Wellbutrin			C	Unknown	Extended Release		Not Reported
	Sulfasalazine			C	Unknown			Not Reported

	Bupropion			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15686123	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573639-00		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S				Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Injection Bp		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported

Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Acetaminophen	C			Not Reported
Anakinra	C	Unknown		Not Reported
Ativan	C			Not Reported
Codeine	C	Unknown		Not Reported
Darifenacin	C			Not Reported
Desoximetasone	C	Oral		Not Reported
Desoximetasone	C	Intramuscular		Not Reported
Dilaudid	C	Unknown		Not Reported
Diphenhydramine	C			Not Reported
Furosemide	C			Not Reported
Hydromorphone	C	Unknown		Not Reported
Kadian	C		Sustained-Release	Not Reported
Kenalog	C	Intra-articular		Not Reported
Kenalog	C			Not Reported
Loperamide	C	Unknown		Not Reported
Norflex	C	Unknown		Not Reported
Omnaris	C	Unknown	Spray,Metered Dose	Not Reported
Oxyneo	C	Unknown	Extended Release	Not Reported
Pantoprazole Sodium	C			Not Reported
Restasis	C	Unknown		Not Reported
Rituxan	C	Intravenous (not otherwise specified)		Not Reported
Synthroid	C	Unknown		Not Reported

Trimethoprim	C	Unknown		Not Reported
Urispas	C			Not Reported
Vagifem	C	Vaginal		Not Reported
Dexamethason	C	Intramuscular		Not Reported
Dyclonine Hydrochloride	C			Not Reported
Enablex	C		(Extended Release)	Not Reported
Pantoprazole Sodium Anhydrous	C			Not Reported
Lasix	C			Not Reported
Morphine Sulphate	C	Unknown		Not Reported
Dyclone	C			Not Reported
Benadryl	C	Unknown		Not Reported
Diphenhydramine Hydrochloride	C	Unknown		Not Reported
Darifenacin Hydrobromide	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Pantoloc	C			Not Reported
Triamcinolone Acetonide	C	Intra-articular		Not Reported
Dexamethasone	C	Unknown		Not Reported
Orphenadrine Citrate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15708189	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2586143-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Incorrect Route Of Product Administration; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Varicella Zoster Vaccine	S	Unknown	Liquid Intramuscular	Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous drip		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15713147	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588025-00		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer Female; Contraindicated Product Administered; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Humira			S	Subcutaneous			Not Reported
	Arava			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15848951	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633323-00		34 YR	Female	CAN

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

Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; Gastric Disorder; General Physical Health Deterioration; Insomnia; Nausea; Rheumatoid Arthritis; Sleep Disorder	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Myochrysine	S	Parenteral	Not Reported
	Otezla	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sirukumab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ustekinumab	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Minocycline	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Orencia	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15923770	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2653534-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase	Humira			S	Subcutaneous			Not Reported

Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported

Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Sulfasalazine	S	Intramuscular	Not Reported
Sulfasalazine	S	Intramuscular	Not Reported
Sulfasalazine	S	Parenteral	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Alendronic Acid	S	Unknown	Not Reported
Myochrysine	S	Unknown	Not Reported
Ciclosporin	C		Not Reported
Prednisone	C	Unknown	Not Reported

	Xeljanz	C	Unknown	Not Reported
	Ciclosporin	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	15932948	EXPEDITED (15-DAY)		HO, LT, OT	CA-ABBVIE-19K-028-2655966-00		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non-	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

Responder; Underdose; Vomiting; Wheelchair User				
	Orencia	S	otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular	Not Reported
	Triamcinolone	S	Intra-articular	Not Reported
	Triamcinolone	S		Not Reported
	Naproxen	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Kineret	S		Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Triamcinolone Acetonide	S		Not Reported
	Triamcinolone Acetonide	S		Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S		Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Adalimumab	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported

	Vaccinia Immune Globulin (Immunoglobulin G Human)	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	16140356	EXPEDITED (15-DAY)		OT	PHHY2019CA070200		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	16403034	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2809805-00		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Plaquenil	S	Oral		Not Reported
	Enbrel	S	Unknown	823	Not Reported
	Enbrel	S	Unknown		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Sulfasalazine	S	Subcutaneous		Not Reported
	Apo Leflunomide	S	Unknown		Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown		Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Tylenol	S	Unknown		Not Reported
	Doxycycline Hyclate	S	Unknown		Not Reported
	Tylenol W/Codeine No. 3	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Acetaminophen And Codeine Phosphate	C			Not Reported
	Methotrexate	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported
	Celebrex	C	Oral		Not Reported
	Leflunomide	C			Not Reported
	Codeine	C			Not Reported
	Celecoxib	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	16408931	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA127221		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Off Label Use; Pharyngitis; Vomiting; Weight Decreased	Voltaren			S	Unknown	Unk		Novartis
	Voltaren			S				Novartis
	Voltaren			S				Novartis
	Voltaren			S				Novartis
	Diclofenac Potassium			S	Unknown			Novartis
	Diclofenac Potassium			S				Novartis
	Diclofenac Potassium			S				Novartis
	Diclofenac Potassium			S				Novartis
	Diclofenac			S	Unknown	Unk		Novartis
	Diclofenac			S				Novartis
	Diclofenac			S				Novartis
	Diclofenac			S				Novartis
	Acetylsalicylic Acid Sandoz			S	Unknown	325 Mg		Not Reported
	Acetylsalicylic Acid Sandoz			S				Not Reported
	Acetylsalicylic Acid Sandoz			S				Not Reported
	Acetylsalicylic Acid Sandoz			S				Not Reported
	Vitamin C			S	Unknown			Not Reported
	Clopidogrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S				Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Gold			S				Not Reported

Gold	S			Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Motrin	S	Unknown		Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S			Not Reported
Plaquenil	S			Not Reported
Plaquenil	S			Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown		Not Reported
Aspirin	S	Oral	Unk	Not Reported
Aspirin	S			Not Reported
Aspirin	S			Not Reported
Aspirin	S			Not Reported
Naprosyn	S	Unknown		Not Reported
Naprosyn	S			Not Reported
Naprosyn	S			Not Reported
Naprosyn	S			Not Reported
Acetylsalicylic Acid W/Clopidogrel	S	Unknown		Not Reported
Apo Sulfatrim	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Oral		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sulphamethoxazole	S	Unknown		Not Reported
Apo-Diclofenac	S	Unknown		Not Reported
Sulfatrim	S	Unknown		Not Reported
Tramadol Hcl	C	Unknown		Not Reported
Tramadol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	16762680	EXPEDITED (15-DAY)		OT	DE-DEXPHARM-20190689			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Quensyl			S	Unknown			Not Reported
	Eliquis			S		2.5 Mg Bid		Not Reported
	Roactemra			S				Not Reported
	Spasmolyt			S				Not Reported
	Spasmolyt			S				Not Reported
	Omeprazole			S	Oral	20 Mg Every 12 Hours: In The Morning And In The Evening		Not Reported
	Ramipril			S	Oral	In The Morning And In The Evening		Not Reported
	Volibris			S				Not Reported
	Sildenafil Citrate			S				Not Reported
	Lyrica			S		100 Mg, Tid		Not Reported
	Pregabalin			S		1 Df, 3x/Day (1 - 1- 1)		Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17271238	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202001000259			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Eye; Dry Mouth; Lower Respiratory Tract Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Salagen			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Vimovo			C		Unk		Not Reported

	Folic Acid	C	Unk	Not Reported
	Vitamin D3	C	25 Ug	Not Reported
	Methotrexate	C	Unk	Not Reported
	Celebrex	C	Unk	Not Reported
	Arthrotec	C	Unk	Not Reported
	Meloxicam	C	Unk	Not Reported
	Omega 3	C	Unk	Not Reported
	Orthotics	C		Not Reported
	Orthotics	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17488060	NON-EXPEDITED			US-PFIZER INC-2020092938		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Back Disorder; Breast Cyst; Bronchitis; Chest Pain; Condition Aggravated; Dyspnoea; Fibromyalgia; Frustration Tolerance Decreased; Insomnia; Joint Swelling; Malaise; Memory Impairment; Musculoskeletal Stiffness; Nodule; Osteoarthritis; Pain; Product Dose Omission; Respiratory Disorder; Weight Increased	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17532940	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA067280			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain;	Cosentyx			S	Unknown	Unk		Novartis

Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Leflunomide	S	Unknown	20 Mg, Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	520 Mg	Not Reported
	Methotrexate	S	Unknown	20 Mg, Unknown	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17658870	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202003001936			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Hydroxychloroquine			S		Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17659181	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202003002316			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Irbesartan			C		Unk		Not Reported
	Lercanidipine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17659505	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030160		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Prescribed Underdose	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb

	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo	Not Reported
	Apo-Azathioprine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Endocervical		Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17659894	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030087		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Pulmonary Fibrosis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qh		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Gold			S	Unknown	Unk		Not Reported

Humira	S	Subcutaneous	40 Milligram, Q2wk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Milligram		Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Risedronate Sodium	S	Unknown	35 Milligram, Qwk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 Gram		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Xeljanz	S	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660024	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020145583		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Incorrect Route Of Product Administration; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Celebrex			S	Unknown			Pfizer
	Enbrel			S	Subcutaneous			Pfizer
	Methotrexate Sodium			S	Unknown			Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	500 Mg, Unk		Pfizer
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, 1 Every 1 Day		Not Reported
	Arava			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisone			S	Endocervical			Not Reported
	Risedronate Sodium			S	Unknown	5 Mg, Unk		Not Reported

	Actemra	S	Unknown		Not Reported
	Cyclobenzaprine	C	Unknown	10 Mg, Unk	Not Reported
	Desoximetasone	C	Unknown	5 Mg, 1x/Day	Not Reported
	Desoximetasone	C	Unknown	5 Mg, Unk	Not Reported
	Leflunomide	C	Unknown		Not Reported
	Prednisone Acetate	C	Unknown	5 Mg,1 Every 1 Day	Not Reported
	Tylenol [Paracetamol]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660039	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020145608			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Blister; Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Lipitor			S	Oral			Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Arthrotec			S				Pfizer
	Cimzia			S		Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Dovobet			C	Topical			Not Reported
	Flovent			C				Not Reported
	Folic Acid			C	Oral			Not Reported
	Multi Vitamin & Mineral			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Ventolin [Salbutamol]			C				Not Reported

	Vitamin D2		C	Oral	1000 Df, Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660080	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147592			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Methotrexate Sodium			S	Unknown			Pfizer
	Myochrysine			S	Unknown			Not Reported
	Aralen [Chloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660089	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147560			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate Sodium			S	Unknown			Pfizer
	Aralen [Chloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660093	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020146051			Female	CAN

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

Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Methotrexate Sodium	S	Oral	Unk	Pfizer
	Methotrexate Sodium	S	Intravenous (not otherwise specified)	Unk	Pfizer
	Celebrex	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Rituximab	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Belimumab	S	Unknown	Unk	Not Reported
	Breo Ellipta	S	Respiratory (inhalation)	Unk	Not Reported
	Colchicine	S	Unknown		Not Reported
	Dexilant	S	Oral	60 Mg, 1x/Day	Not Reported
	Estrogel	S	Topical	Unk Unk, 1x/Day	Not Reported
	Meloxicam	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Mg, 2x/Day	Not Reported
	Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Ventolin Hfa	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660317	NON-EXPEDITED			US-PFIZER INC-2020147388		38 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Effective For Unapproved Indication; Off Label Use; Product Use In Unapproved Indication; Therapeutic Response Unexpected	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660569	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147922			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Uveitis	Methotrexate Sodium			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Aralen Hydrochloride			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Myochrysine			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661320	DIRECT	Y	OT			40 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Electrocardiogram Qt Prolonged; Transaminases Increased	Hydroxychloroquine			S	Oral			Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661328	DIRECT	Y	OT			51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Hydroxychloroquine			S	Oral			Not Reported
	Lopinavir/Ritonavir			S				Not Reported
	Atorvastatin 80mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661548	EXPEDITED (15-DAY)		OT	NVSC2020CA096823		51 YR	Female	CAN

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

Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Neoral	S	Oral	Unk	Novartis
	Neoral	S	Subcutaneous	Unk	Novartis
	Rituximab	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate Disodium	S	Subcutaneous	25 Mg, Qw	Not Reported
	Methotrexate Disodium	S	Oral	20 Mg, Qw	Not Reported
	Ciclosporin Sandoz	S	Subcutaneous	Unk	Novartis
	Adalimumab	S	Subcutaneous	40 Mg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
	Apo-Hydroxyquine	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q2w	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2w	Not Reported
	Hydroxychloroquine	S	Oral	20 Mg	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	20 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Orencia	S	Unknown	75 Mg, Qmo	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
	Sulfasalazine	S			Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Avara	C	Oral	20 Mg, Qd	Not Reported

Rituxan	C	Unknown	500 Mg, Qd		Not Reported
Cimzia	C	Subcutaneous	200 Mg, Q2w		Not Reported
Risedronate	C	Oral	25 Mg, Qw		Not Reported
Risedronate	C	Oral	30 Mg, Qw		Not Reported
Plaquenil	C	Oral	200 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661837	EXPEDITED (15-DAY)		OT	NVSC2020CA097860		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin Sandoz			S	Unknown			Novartis
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Every 1 Week		Not Reported
	Humira			S	Subcutaneous			Not Reported

	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661903	DIRECT	Y	LT			47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged	Plaquenil			S				Not Reported
	Azithromycin Tablet			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17661978	EXPEDITED (15-DAY)		DS	BR-ADVANZ PHARMA-202003002616			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bedridden	Hydroxychloroquine			S	Unknown	Unk, 2x15, Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662028	EXPEDITED (15-DAY)		OT	BR-ADVANZ PHARMA-202003002623			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Dependence; Off Label Use	Hydroxychloroquine			S	Oral	1 Dosage Form, Qd, Coated Tablet		Concordia
	Puran T4			C		Unk		Not Reported
	Pregabalin			C		50 Mg		Not Reported
	Pregabalin			C				Not Reported
	Pregabalin			C				Not Reported
	Pregabalin			C				Not Reported
	Alektos			C		20 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662053	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1223033		54 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Azithromycine Anhydre			S	Oral	Unknown Dosage		Not Reported
	Plaquenil			S	Oral	800 Mg		Not Reported
	Augmentin			C	Oral	Unknown Dosage		Not Reported
	Hypnovel			C				Not Reported
	Sufentanil			C				Not Reported
	Etomidate			C				Not Reported
	Tracrium			C				Not Reported
	Esmeron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662107	EXPEDITED (15-DAY)		OT	NVSC2020CA097244		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported

	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	C	Oral	5 Mg, Qd (2 Every 1 Days)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662141	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002380			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatocellular Injury	Hydroxychloroquine			S	Oral	400 Mg, Qd (Fiim-Coated Tablet)		Concordia
	Enoxaparin			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662224	EXPEDITED (15-DAY)		DE, HO, OT	SK-GLAXOSMITHKLINE-SK2020061907		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Intentional Product Use Issue; Jc Virus Infection; Mental Impairment; Off Label Use; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure;	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Azathioprine			S	Unknown	Unk		Glaxosmithkline
	Cyclosporine A			S	Unknown	Unk		Glaxosmithkline
	Methotrexate			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

Speech Disorder; Tremor	Prednisone	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662227	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-202003002617			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cutaneous Lupus Erythematosus; Stress	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662281	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002582			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662417	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003003386			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			S	Unknown	Unk		Not Reported
	Zinc Salt Nos			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662684	EXPEDITED (15-DAY)		OT	NVSC2020US098481			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinopathy	Hydroxychloroquine			S	Unknown	(1.2-8.3) Mg/Kg		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662798	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1222453		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Cardiomyopathy	Hydroxychloroquine			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663000	EXPEDITED (15-DAY)		OT	NVSC2020CA098112			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Dactylitis; Drug Ineffective; Enthesopathy; Inflammation; Joint Stiffness; Psoriasis; Psoriatic Arthropathy; Tenosynovitis; Vertigo	Cosentyx			S	Unknown	300 Mg, Qmo		Novartis
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Prednisone			C	Oral	10 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663200	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202003002813			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk (Film-Coated Tablet)		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663224	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002823			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

	Nivaquine			S	Unknown	1 Dosage Form, Qd			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663282	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202004002844			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Disorder; Fall; Femur Fracture; Hypoacusis; Intentional Product Use Issue; Product Dose Omission; Unevaluable Event	Hydroxychloroquine			S	Unknown	2cp/Day, Qd		Concordia
	Hydroxychloroquine			S		1cp/Day For 15		Concordia
	Cardensiel			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663302	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004002921			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663508	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3361937-00			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663522	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3362044-00			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Kaletra 200/50			S	Oral			Not Reported

	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663539	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3362011-00			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17665337	DIRECT	Y	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Transaminases Increased	Hydroxychloroquine Oral Tablet			S	Oral			Not Reported
	Lopinavir/Ritonavir			S	Oral			Not Reported
	Atorvastatin 40mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17665521	DIRECT	Y	DE, HO			79 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Test Positive	Hydroxychloroquine 200mg Po			S	Oral			Actavis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	11925949	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ABBVIE-15K-028-1444053-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported

Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Myocardial Infarction; Near Death Experience; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Gold	S	Subcutaneous	Not Reported
	Gold	S		Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Methotrexate Sodium	S		Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S		Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Arava	S	Unknown	Not Reported

Arava	S			Not Reported
Medical Marijuana	S	Unknown		Not Reported
Minocycline	S	Unknown		Not Reported
Oxycodone Hydrochloride	S	Unknown		Not Reported
Xeljanz	S	Oral		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Anakinra	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S			Not Reported
Oxycodone	S	Unknown		Not Reported
Cannabis Sativa	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S			Not Reported
Kineret	C			Not Reported
Rituximab	C			Not Reported
Kineret	C	Unknown		Not Reported
Lyrica	C	Unknown		Not Reported
Ilaris	C	Subcutaneous	Single-Use Vial	Not Reported
Rituximab W/Urelumab	C	Unknown		Not Reported
Anakinra	C	Unknown		Not Reported
Urelumab	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	12881921	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013278			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Naproxen Sodium Tablets			S	Unknown			Not Reported

Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Apotex
	Prednisone	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S			Apotex
	Naproxen Sodium	S	Unknown	Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Aleve	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Unknown	12.5 Mg, Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Subcutaneous	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	13054285	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015721			Female	CAN

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

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide	S	Oral	Unk	Apotex
	Hydroxychloroquine	S	Oral	Unk	Apotex
	Apo-Leflunomide	S	Unknown	Unk	Apotex
	Actemra	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Actemra	C	Subcutaneous	Unk	Not Reported
	Enbrel	C	Subcutaneous	Unk	Not Reported
	Humira	C	Unknown	40 Mg, Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Orencia	C	Unknown	Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	13976362	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018043		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	25 Mg, Q.Wk.		Apotex
	Actemra			S	Unknown	Unk		Not Reported

Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Arava		S	Unknown	25 Mg, Q.Wk.	Not Reported
	Enbrel		S	Unknown	50 Mg, Q.Wk.	Not Reported
	Humira		S	Subcutaneous	Unk	Not Reported
	Methotrexate		S	Oral	25 Mg, Q.Wk.	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate		S	Unknown	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14144042	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020346		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Spinal Stenosis; Synovitis	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported

Humira	S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
Humira	S	Subcutaneous	40 Mg		Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Mg, Once Every Four Weeks		Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Mg, Unk 1 Every 4 Months		Not Reported
Orencia	S	Unknown	500 Unk, Unk		Not Reported
Methotrexate	S	Unknown	20 Mg, Q.Wk.		Not Reported
Methotrexate	S	Oral	Unk		Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	5 Mg, Bid		Not Reported
Xeljanz	C	Unknown	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14243063	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Winpred			S	Oral	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg, Unk		Not Reported

Cortisone Acetate	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Reactine /00884302/	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14243135	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021933		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Osteoarthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Leflunomide			S	Unknown	10 Mg, Q.O.D.		Apotex

Leflunomide	S	Unknown	5 Mg, Q.O.D.	Apotex
Leflunomide	S	Unknown	10 Mg, Qd	Apotex
Doxycycline	S	Unknown	50 Mg, Unk	Apotex
Actemra	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Unknown	Unk, Q.Wk.	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	0.8 Mg, Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Methotrexate Sodium	S	Unknown	15 Mg, Q.Wk.	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14404773	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005233			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

Enbrel	S	Subcutaneous	Unk		Not Reported
Fosamax	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Reactine /00884302/	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14558788	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2262991-00			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Gold			S	Other			Not Reported

Plaquenil	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	14746352	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009049			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Cyclosporine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	125 Mg, Q.Wk.		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Tylenol Arthritis Pain			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15132896	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2018014806			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Pantoprazole			S	Transplacental	40 Milligram, Qd, 40 [Mg/D]; 0-13.6 Gestational Week		Macleods
	Pantoprazole			S	Transplacental	Unk		Macleods
	Aspirin			S	Transplacental	100 Milligram, Qd, From Gestational Week 0-14		Not Reported
	Aspirin			S	Transplacental	Unk		Not Reported
	Prednisolone			S	Transplacental	10 Milligram, Bid, Tablet, From Gestational Week 0-14		Not Reported
	Simvastatin			S	Transplacental	Unk		Not Reported
	Simvastatin			S	Transplacental	Unk, Tablet, From Gestational Week 0-14		Not Reported
	Tacrolimus			S	Transplacental	6 Milligram, Qd, From Gestational Week 0-14		Not Reported
	Tacrolimus			S	Transplacental	Unk, 1 Trimester		Not Reported
	Tacrolimus			S	Transplacental	Unk		Not Reported
	Heparins, Low-Molecular-Mass			S	Transplacental	Unk		Not Reported
	Heparins, Low-Molecular-Mass			S	Transplacental	Unk		Not Reported
	Salbutamol Sulfate			S	Transplacental	Unk Unk, Qd, From Gestational Week 0-14		Not Reported
	Salbutamol Sulfate			S	Transplacental	Unk		Not Reported
	Metamizole Sodium			S	Transplacental	Unk		Not Reported
	Metamizole Sodium			S	Transplacental	Unk,From Gestational Week 0-14		Not Reported
	Nicotine			S	Transplacental	Unk		Not Reported
	Nicotine			S	Transplacental	Unk, From Gestational Week 0-14		Not Reported
	Ramipril			S	Transplacental	20 Milligram, From Gestational Week 0-13+6 Weeks) Maternal Dose 20 Mg		Not Reported

Hydroxychloroquine	S	Transplacental	400 Milligram, Qd, From Gestational Week 0-14	Not Reported
Aliskiren	S	Transplacental	300 Milligram, Qd, 300 [Mg/D]; 0-4.6 Gestational Week	Not Reported
Aliskiren	S	Transplacental	Unk	Not Reported
Rivaroxaban	S	Transplacental	Unk	Not Reported
Rivaroxaban	S	Transplacental	Unk	Not Reported
Ezetimibe	S	Transplacental	Unk, Tablet, From Gestational Week 0-14	Not Reported
Ezetimibe	S	Transplacental	Unk	Not Reported
Torasemide	S	Transplacental	100 Mg Qd From Gestational Week 0-14	Not Reported
Xarelto	S	Transplacental	Unk, Film Coated Tablet,From Gestational Week 0-5	Not Reported
Clexane	S	Transplacental	200 Milligram, Qd, 2 X 100	Not Reported
Dalteparin Sodium	S	Transplacental	Unk	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional, Trimester: Preconceptional	Not Reported
Rasilez	S	Unknown		Not Reported
Enoxaparin Sodium	S	Transplacental	Unk, From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid	S	Transplacental	100 Milligram, Qd	Not Reported
Novaminsulfon	S	Transplacental	Unk, Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Mifegyne	C	Transplacental	Unk, 13.6 Gestational Week	Not Reported
Cyclophosphamide	C	Transplacental	Unk, 3000 [Mg	Not Reported

Cumulative];
Preconceptional

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15337014	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019548		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk, Therapy Duration: 59		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Meloxicam			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	160 Mg, Q.Wk.		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	80 Mg, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15622524	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557260-00		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Off Label Use	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Diclofenac			C				Not Reported
	Desoximetasone			C	Oral			Not Reported
	Xeljanz			C	Subcutaneous			Not Reported
	Zostavax			C	Subcutaneous			Not Reported
	Methotrexate			C				Not Reported
	Voltaren			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15629606	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555539-00		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Administered; Cough; Cough; Diarrhoea; Diarrhoea; Drug Ineffective; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Headache; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Actemra	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Prednisone	C		Not Reported
	Prevacid	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15670302	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2571378-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel	Humira			S	Subcutaneous			Not Reported
	Mefenamic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	1 Dosage Forms	Not Reported
	Enbrel	S	Subcutaneous	1 Dosage Forms	Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S			Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S			Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Prednisone	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Tylenol	C	Unknown		Not Reported
	Advil	C			Not Reported
	Dequalinium Chloride	C	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	15806693	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2618205-00		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Myochrysine	S	Parenteral	Foa-Solution Inramuscular	Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Foa-Solution Intravenous	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Codeine	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Alendronate	S	Unknown		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Etanercept	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Alendronic Acid	S	Unknown		Not Reported
Alendronate Sodium	S	Unknown		Not Reported

	Codeine Sulfate	S	Unknown		Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported
	Ciclosporin	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	16079861	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06082		41 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Fatigue; General Physical Health Deterioration; Granuloma Skin; Headache; Hepatic Enzyme Increased; Hypercalcaemia; Hypersensitivity; Infection; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Etanercept			S	Unknown	Unknown		Not Reported
	Etanercept			S				Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral	Unknown		Not Reported
	Apremilast			S	Oral			Not Reported
	Apremilast			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous	Unknown		Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Ciclosporin			S	Subcutaneous	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown (Solution), Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unknown (Solution)		Not Reported
	Golimumab			S	Subcutaneous	Unknown		Not Reported
	Motrin			S	Oral			Not Reported

Inflammation; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer	Motrin	S	Unknown		Not Reported
	Orencia	S	Subcutaneous	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Otezla	S	Oral		Not Reported
	Otezla	S	Unknown	Unknown	Not Reported
	Otezla	S			Not Reported
	Simponi	S	Subcutaneous	Unknown (Solution)	Not Reported
	Stelara	S	Subcutaneous	Unknown (Solution)	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Ustekinumab	S	Subcutaneous	Unknown	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Unknown		Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Sulfamethoxazole	S	Oral		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Apo-Cyclosporine	S	Oral	Unknown	Not Reported
	Codeine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Colchicine	C	Oral		Not Reported
	Febuxostat	C	Unknown		Not Reported
	Febuxostat	C	Unknown		Not Reported
	Folic Acid	C	Unknown	Unknown	Not Reported
	Methotrexate	C	Unknown		Not Reported

Methotrexate	C	Unknown		Not Reported
Methotrexate	C	Oral	Unknown	Not Reported
Methotrexate	C	Unknown	Unknown	Not Reported
Mogadon	C	Unknown		Not Reported
Nitrazepam	C	Oral		Not Reported
Oxycodone Hydrochloride	C	Unknown		Not Reported
Oxycodone Hydrochloride	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported
Oxyneo	C	Unknown	(Extended Release)	Not Reported
Uloric	C	Oral		Not Reported
Benadryl	C	Unknown	Unknown	Not Reported
Dexilant	C	Unknown	Unknown (Delayed Release)	Not Reported
Dexilant	C	Unknown	Unknown, Prolonged Release	Not Reported
Gravol	C	Unknown	Unknown	Not Reported
Oxycodone	C	Unknown		Not Reported
Oxycodone	C	Unknown		Not Reported
Acide Folique	C	Unknown	Unknown	Not Reported
Methotrexate Sodium	C	Oral		Not Reported
Prednisone	C	Unknown	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	16589246	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2851920-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis;	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Therapeutic Product Effect Decreased	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Desoximetasone	C		Not Reported
	Gold	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	16954774	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2972637-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Test Abnormal; Inflammation; Local Reaction; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Syncope; Vomiting	Humira			S	Subcutaneous			Not Reported
	Plantago Afra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Aclasta			S	Intravenous (not otherwise specified)			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Hydrochlorothiazide			C				Not Reported
	Ergocalciferol			C				Not Reported
	Folic Acid			C				Not Reported

	Cannabis Sativa	C			Not Reported
	Tums	C			Not Reported
	Lipitor	C			Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Calcium Carbonate	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17223484	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3215049-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Simponi			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17450609	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007837		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Drug	Hydroxychloroquine			S	Unknown	200 Mg, Q.12h		Apotex

Ineffective; Thrombosis	Leflunomide	S	Unknown	10 Mg, Qd		Apotex
	Methotrexate	S	Oral	15 Mg, Q.Wk.		Not Reported
	Sulfasalazine	C	Unknown	1000 Mg, Bid		Not Reported
	Sulfasalazine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17543919	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA072124		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Bid		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unknown		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unknown		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	5 Mg, Bid		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported

Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Endocervical	400 Mg	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone Acetate	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	2 Df, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Folic Acid	C	Subcutaneous	Unk	Not Reported
Insulin	C	Oral	Unk (Drops)	Not Reported
Metformin	C	Unknown	2 Df, Bid	Not Reported
Metformin	C	Unknown	1 Unk	Not Reported
Plaquenil	C	Unknown		Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17552068	EXPEDITED (15-DAY)		HO, OT	JP-GLAXOSMITHKLINE-JP2020JPN044468		40 YR	Female	JPN

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

Cytomegalovirus Infection	Belimumab	S	Intravenous drip	Unk	Glaxosmithkline
	Belimumab	S	Intravenous drip	10 Mg/Kg, Once In Every Four Weeks	Glaxosmithkline
	Belimumab	S	Intravenous drip	10 Mg/Kg, Once In Every Four Weeks	Glaxosmithkline
	Prednisolone	S	Oral	Unk	Glaxosmithkline
	Prednisolone	S	Oral	10 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	9 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	8 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	7 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	6 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	7 Mg, 1d	Glaxosmithkline
	Prednisolone	S	Oral	8 Mg, 1d	Glaxosmithkline
	Tacrolimus	S	Unknown	Unk	Glaxosmithkline
	Imuran	S	Unknown	Unk	Glaxosmithkline
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Bonoteo	C		Unk	Not Reported
	Lansoprazole	C		Unk	Not Reported
	Bayaspirin	C		Unk	Not Reported
	Rebamipide	C		Unk	Not Reported
	Baktar	C		Unk	Not Reported
	Colonel	C		Unk	Not Reported
	Loxofen (Loxoprofen Sodium)	C		Unk	Not Reported
	Amerge	C		Unk	Not Reported
	Sumilu Stick	C		Unk	Not Reported
	Celecox	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17572131	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332786		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulitis; Therapeutic Product Effect Incomplete	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S				Not Reported
	Arava			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Plaquenil /00072602/			S				Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17594562	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332781		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Treatment Failure; White Blood Cell Count Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17605651	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332787		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Syncope; Urticaria	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17605666	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332776		34 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Stelara			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Minocycline Hydrochloride	S		Not Reported
Myochrysine	S	Intramuscular	Not Reported
Otezla	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Salazopyrin	S	Unknown	Not Reported
Sirukumab	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Methotrexate	C	Unknown	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17636246	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-PBT-000165			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S	Transplacental			Panacea Biotec
	Tacrolimus			S	Transplacental			Panacea Biotec
	Tacrolimus			S	Transplacental			Panacea Biotec
	Rivaroxaban			S	Transplacental			Not Reported
	Rivaroxaban			S	Transplacental			Not Reported
	Nicotine			S	Transplacental			Not Reported
	Simvastatin			S	Transplacental			Not Reported
	Acetylsalicylic Acid			S	Transplacental			Not Reported
	Acetylsalicylic Acid			S	Transplacental			Not Reported

	Pantoprazole	S	Transplacental	Not Reported
	Pantoprazole	S	Transplacental	Not Reported
	Torasemide	S	Transplacental	Not Reported
	Ramipril	S	Transplacental	Not Reported
	Ramipril	S	Transplacental	Not Reported
	Aliskiren	S	Transplacental	Not Reported
	Prednisolone	S	Transplacental	Not Reported
	Prednisolone	S	Transplacental	Not Reported
	Dipyrone	S	Transplacental	Not Reported
	Dipyrone	S	Transplacental	Not Reported
	Hydroxychloroquine Sulfate	S	Transplacental	Not Reported
	Heparin	S	Transplacental	Not Reported
	Heparin	S	Transplacental	Not Reported
	Salbutamol Sulfate	S	Transplacental	Not Reported
	Salbutamol Sulfate	S	Transplacental	Not Reported
	Ezetimibe	S	Transplacental	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17656876	EXPEDITED (15-DAY)		LT	US-PFIZER INC-2020148479		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Azithromycin			S	Oral	500 Mg, Daily (500 Mg On Day 1)		Pfizer
	Azithromycin			S	Oral	250 Mg, Daily (Followed By 250 Mg Daily For 4 Days)		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 2x/Day (400 Mg Twice Daily On Day 1)		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day (Followed By 400 Mg Daily For 4 Days)		Not Reported

	Ceftriaxone		C	Intravenous (not otherwise specified)	1 G, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17663632	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018207		52 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day (Dia)		Aurobindo
	Azithromycin			S				Aurobindo
	Paracetamol			S	Oral	1 Gram, 3 Times A Day (1gr Cada 8 Horas)		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day (Dia)		Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day (Dia)		Not Reported
	Dolquine			S				Not Reported
	Simvastatina Alter			S	Oral	0-0-1		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17663750	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201706-003792			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Apoleflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

Orencia	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Leflunomide	S	Oral	Unk		Not Reported
Xeljanz	C		Unk		Not Reported
Prednisone	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17663778	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147529		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Enbrel			S	Subcutaneous	40 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Monthly		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Endocervical	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	0.75 Mg, Monthly		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Prednisone			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17663950	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021948		53 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Hypersensitivity	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Apremilast			S	Unknown	30 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Oral	30 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	30 Mg, Bid		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664171	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1698			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664175	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased; Renal Impairment	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664213	EXPEDITED (15-DAY)		DE	ES-ABBVIE-20K-144-3361763-00		95 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Kaletra 200/50			S	Oral			Not Reported
	Quetiapina			S	Oral			Not Reported
	Levofloxacino			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Risperidona			S	Oral			Not Reported
	Losartan			C	Oral			Not Reported
	Clindamicina Hidrocloruro			C	Intravenous (not otherwise specified)			Not Reported
	Lorazepam			C	Oral			Not Reported
	Furosemida			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664281	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664285	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1705			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Neuropathy Peripheral	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Codeine Phosphate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664555	EXPEDITED (15-DAY)		OT	HK-ACCORD-178663		67 YR	Female	HKG

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Tuberculosis	Methotrexate			S				Accord
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17665011	NON-EXPEDITED			US-PFIZER INC-2020152441		50 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Off Label Use	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17665208	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020145791		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Xeljanz			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Calcium/Vitamin D3			C		Unk		Not Reported
	Hydrocortisone			C		Unk Unk, 2x/Day		Not Reported
	Pantoloc [Pantoprazole]			C		Unk		Not Reported

	Prednisone	C	20 Mg, 1x/Day	Not Reported
	Tylenol Arthritis Pain	C	2 Df, 2x/Day	Not Reported
	Xarelto	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17665283	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021759		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Treatment Failure	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Subcutaneous	Unk		Apotex
	Hydroxychloroquine			S	Subcutaneous	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported

	Neoral	S	Oral	Unk		Not Reported
	Neoral	S	Oral	Unk		Not Reported
	Plaquenil /00072602/	S	Unknown	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17665668	NON-EXPEDITED		HO, OT	NVSC2020US099010		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Chest Pain; Cough; Decreased Appetite; Dyspnoea; Hepatitis Viral; Nausea; Pyrexia	Prednisone			S	Unknown	5 Mg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Metronidazole			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17665946	EXPEDITED (15-DAY)		DE, HO, OT	SK-HORIZON-PRE-0109-2020		57 YR	Male	SVK

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Dizziness; Hypotension; Intentional Product Use Issue; Jc Virus Infection; Mental Impairment; Off Label Use; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Prednisone			S				Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Cyclosporine A			S				Not Reported
	Methotrexate			S				Not Reported
	Belimumab			S				Not Reported
	Cyclophosphamide			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17666426	EXPEDITED (15-DAY)		OT	NVSC2020PT099374		48 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17666598	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-GSH201712-006550			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	750 Mg Every Other Week		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Celebrex			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17667117	EXPEDITED (15-DAY)		OT	NVSC2020CA098733			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthritis; Bone Erosion; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Exostosis; Foot Deformity; Hepatic Cirrhosis; Joint Dislocation; Joint Stiffness; Off Label Use; Osteoarthritis; Osteoporosis; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported

	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sirukumab	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Dilaudid	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17667548	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2375555-00		56 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Inflammation; Joint Swelling;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Certolizumab			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	C		Not Reported
	Xeljanz	C		Not Reported
	Leucovorin Calcium	C		Not Reported
	Codeine	C		Not Reported
	Ibuprofen	C		Not Reported
	Dilaudid	C		Not Reported
	Plaquenil	C		Not Reported
	Acetaminophen	C		Not Reported
	Ventolin Hfa	C		Not Reported
	Nexium Dr	C		Not Reported
	Advair Diskus	C		Not Reported
	Allopurinol	C		Not Reported
	Cyclobenzaprine Hcl	C		Not Reported
	Atrovent Hfa	C		Not Reported
	Hydromorphone Hcl	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17667774	EXPEDITED (15-DAY)		OT	NVSC2020CA098830			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nausea; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; White Blood Cell Count Decreased	Cosentyx			S	Unknown	150 Mg, Unknown		Novartis
	Methotrexate			S	Oral	15 Mg, Unknown		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unknown		Not Reported
	Otezla			S	Oral	30 Mg, Bid		Not Reported
	Sulfasalazine			C	Unknown	1 G, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17667856	EXPEDITED (15-DAY)		OT	NVSC2020CA098863		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Erythromycin			C	Unknown	Unk		Not Reported
	Morphine			C	Topical	Unk		Not Reported
	Methotrexate			C	Oral	1 Df, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668265	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-017705			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668362	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3362555-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Polyarthritis; Skin Lesion; Uveitis	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

	Plaquenil	S	Unknown	Not Reported
	Aralen	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668434	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030217		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, 1 Every 2 Weeks, Duration 1 Days And 15 Days		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, 1 Every 2 Weeks, Duration 2.0 Years		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Days		Not Reported
	Leflunomide			S	Oral	10 Milligram, Duration 2 Months		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, 1 Every 1 Week, Duration 2 Months		Not Reported
	Plaquenil S			S	Unknown	200 Milligram, 2 Every 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

Amlodipine	C	Unknown	Unk		Not Reported
Arava	C	Unknown	Unk		Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk		Not Reported
Methotrexate	C	Unknown	Unk		Not Reported
Naproxen	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Unknown	5 Milligram, 2 Every 1 Days		Not Reported
Viread	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668438	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-017975		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Resistance; Product Use In Unapproved Indication	Clindamycin			S	Unknown	300 Milligram, Two Times A Day		Aurobindo
	Rifampin			S	Unknown	600 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Two Times A Day (Monday Through Friday)		Not Reported
	Clobetasol			S	Unknown	Unk Unk, Two Times A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17669671	DIRECT					54 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angiopathy; Anxiety; Burning Sensation; Fatigue; Muscle Spasms; Nervous System Disorder;	Hydroxychloroquine Sulfate Plaquenil			S	Oral	Quantity:1 Tablet(S);	4 DAY	Not Reported

Nonspecific Reaction;
Pain Of Skin; Pruritus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	8792714	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-009507513-1209DEU004039			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Simvastatin			S	Transplacental	Unk		Merck
	Simvastatin			S	Transplacental	From Gestational Week 0-14		Merck
	Viemm 10 Mg Tabletten			S	Transplacental	From Gestational Week 0-14		Merck
	Aspirin			S	Transplacental	From Gestational Week 0-14		Not Reported
	Pantoprazole			S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week		Not Reported
	Prednisolone			S	Transplacental	From Gestational Week 0-14		Not Reported
	Enoxaparin Sodium			S	Transplacental	From Gestational Week 0-14		Not Reported
	Albuterol			S	Transplacental	From Gestational Week 0-14		Not Reported
	Torsemide			S	Transplacental	From Gestational Week 0-14		Not Reported
	Novaminsulfon			S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5		Not Reported
	Aliskiren			S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week		Not Reported
	Dipyrone			S	Transplacental	From Gestational Week 0-14		Not Reported
	Ramipril			S	Transplacental	20 Mg Unk From Gestational Week 0-113+6		Not Reported
	Xarelto			S	Transplacental	From Gestational Week 0-		Not Reported

				5	
	Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
	Dalteparin Sodium	S	Transplacental	Unk	Not Reported
	Heparin	S	Transplacental	Unk	Not Reported
	Clexane (Enoxaparin Sodium)	S	Transplacental	200 Mg/D (2x100)	Not Reported
	Hydroxychloroquine Sulfate	S	Transplacental	From Gestational Week 0-14	Not Reported
	Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
	Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
	Tacrolimus	S	Transplacental	From Gestational Week 0-14	Not Reported
	Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
	Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported
	Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	12891950	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOPHARMA INC-2016AP013468			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S				Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S				Apotex

Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
Sulfasalazine	S				Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Methotrexate	S				Not Reported
Actemra	S	Unknown	Unk		Not Reported
Actemra	S				Not Reported
Anakinra	S	Unknown	Unk		Not Reported
Anakinra	S				Not Reported
Enbrel	S	Subcutaneous	Unk		Not Reported
Enbrel	S				Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Humira	S				Not Reported
Ilaris	S	Subcutaneous	Unk		Not Reported
Ilaris	S	Unknown	Unk Unk, Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Remicade	S				Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S				Not Reported
Rituximab	S	Unknown	Unk		Not Reported
Rituximab	S				Not Reported
Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	13059562	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015791		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Back Disorder; Condition Aggravated;	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex

Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Spinal Stenosis; Synovitis; Vasculitic Rash	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Apotex
	Hydroxychloroquine	S	Unknown	200 Mg, Qd	Apotex
	Apo-Leflunomide	S	Oral	20 Mg, Qd	Apotex
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
	Anakinra	S	Subcutaneous	100 Mg, Qd	Not Reported
	Anakinra	S	Subcutaneous	100 Mg, Unk	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.,	Not Reported
	Humira	S	Subcutaneous	Unk, Q.Wk.	Not Reported
	Humira	S	Unknown	40 Mg, Cyclical	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.,	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	20 Mg, Q.O.Wk.	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Q.O.Wk.	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Unk, Once Every 4 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	500 Mg, Cyclical	Not Reported

	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Cyclical	Not Reported
	Kineret	S	Subcutaneous	100 Mg, Qd	Not Reported
	Methotrexate Sodium	S	Oral	12.5 Mg, Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Unk	Not Reported
	Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
	Xeljanz	C	Unknown	5 Mg, Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	13059788	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP015748		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ilaris			C	Unknown			Not Reported

Plaquenil /00072602/	C	Unknown	Unk		Not Reported
Rituximab	C				Not Reported
Methotrexate	C	Unknown	Unk		Not Reported
Anakinra	C	Unknown	Unk		Not Reported
Hydroxychloroquine	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	13254993	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP006561		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Arthralgia; Arthropathy; Bone Cyst; Crohn'S Disease; Deafness Neurosensory; Deformity; Diarrhoea; Drug Ineffective; Dry Eye; Exostosis; Fatigue; Hypersensitivity; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbyacusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Fentanyl			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	488 Mg,Once Every Four Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Q.M.T.		Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.I.W		Not Reported
	Methotrexate			S	Subcutaneous	Unk, Q.I.W		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Once Every 4 Weeks		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Q.M.T.		Not Reported
	Orencia			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Oxycontin			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2.5 G, Qd		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported
	Actonel			C	Unknown	36 Mg, Q.Wk.		Not Reported
	Calcium			C	Unknown			Not Reported

Diphenoxylate Hydrochloride	C	Unknown			Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Unk		Not Reported
Gabapentin	C	Oral	100 Mg, Bid		Not Reported
Genteal /00445101/	C	Unknown			Not Reported
Lomotil /00034001/	C	Unknown	2.5 Mg, Unk		Not Reported
Nasonex	C	Unknown	Unk, Bid		Not Reported
Nexium /01479302/	C	Unknown	40 Mg, Bid		Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Q.H.		Not Reported
Omega 3 /01334101/	C	Unknown	1200 Mg, Bid		Not Reported
Prednisone	C	Unknown	5 Mg, Unk		Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Q.H.		Not Reported
Tylenol /00020001/	C	Oral	1000 Mg, Unk		Not Reported
Vitamin D /00107901/	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	14235439	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Abatacept			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15076484	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015974			Female	CAN

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

Arthralgia; Arthritis; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Leflunomide	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Adalimumab	S	Subcutaneous	40 Mg, Unk	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Unk 1 Every 14 Days	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Unk 1 Every 10 Days	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk 1 Every 10 Days	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk 1 Every 14 Days	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tofacitinib	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Kevzara	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rabeprazole Sodium	C	Oral	20 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15391128	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-955090		84 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pruritus; Rash Maculo-Papular	Repaglinide			S	Oral			Actavis
	Perindopril			S	Oral			Not Reported
	Perindopril			S	Unknown			Not Reported
	Plaquenil			S	Oral	200 Mg/ Day		Not Reported
	Cortancyl			S	Oral	20 Milligram Daily; 10-20µg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15625329	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558387-00		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Duration:365.0		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Prednisone	C	Endocervical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15751882	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181226205		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Decreased Appetite; Drug Ineffective; Exposure During Pregnancy; Fatigue; General Physical Health Deterioration; Glossodynia; Headache; Hypersensitivity; Hypertension; Hypoaesthesia; Joint Swelling; Malaise; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Simponi			S	Intravenous (not otherwise specified)			Janssen
	Stelara			S	Subcutaneous			Janssen
	Stelara			S				Janssen
	Reactine Unspecified (Cetirizine Dihydrochloride)			S	Unknown			Johnson And Johnson
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Otezla	S	Oral	Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown	Not Reported
Topicort /00370301/	S	Unknown	Not Reported
Salazopyrine	C	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Desoximetasone	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Dexamethasone	C	Unknown	Not Reported
Acetaminophen W/Dextropropoxyphene	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15760613	NON-EXPEDITED			US-PFIZER INC-2018522861		77 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Heparin Sodium			S		Unk		Pfizer
	Lisinopril			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Duloxetine			S	Oral	100 Mg, Daily		Not Reported
	Insulin			C		Unk		Not Reported
	Januvia			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Losartan/Hctz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15819449	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-DRREDDYS-GER/GER/19/0106738			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Pantoprazole			S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week		Not Reported
	Ezetimibe			S	Transplacental			Not Reported
	Ezetimibe			S	Transplacental	From Gestational Week 0-14		Not Reported
	Ramipril			S	Transplacental	20 Mg Unk From Gestational Week 0-113+6		Not Reported
	Simvastatin			S	Transplacental	From Gestational Week 0-14		Not Reported
	Torasemide			S	Transplacental	From Gestational Week 0-14		Not Reported
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Not Reported
	Salbutamol			S	Transplacental	From Gestational Week 0-14		Not Reported
	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Not Reported

Xarelto	S	Transplacental	From Gestational Week 0-5 082(Film Coated Tablet)	Not Reported
Aliskiren	S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week	Not Reported
Dalteparin Sodium	S	Transplacental		Not Reported
Heparin (Salt Not Specified)	S	Transplacental	Unk Unk,Unk	Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Enoxaparin Sodium	S	Transplacental	200 Mg/D (2x100)	Not Reported
Rituximab	S	Transplacental	Last Time In December 2011: Pre Or Periconceptional	Not Reported
Clexane	S	Transplacental	200 Mg/D (2x100)	Not Reported
Heparin Lmw	S	Transplacental	Unk	Not Reported
Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
Metamizole	S	Transplacental	From Gestational Week 0-14	Not Reported
Prednisolone	S	Transplacental	From Gestational Week 0-14	Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported
Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	15933671	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656078-00			Female	CAN

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

Breast Cancer Female; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Humira	S	Subcutaneous		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Solution	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Leflunomide	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Gold	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sulfasalazine	C			Not Reported
	Meloxicam	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	16695071	EXPEDITED (15-DAY)		OT	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-079550			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Apixaban			S	Unknown	2.5 Milligram, Bid		Bristol Myers Squibb
	Apixaban			S	Unknown	2 Dosage Form, Qd		Bristol Myers Squibb
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Lyrica			S	Unknown	100 Milligram, Tid		Not Reported
	Quensyl			S	Unknown	40 Milligram, Bid		Not Reported
	Quensyl			S	Unknown	20 Milligram, Bid		Not Reported

	Roactemra	S	Subcutaneous	162 Milligram, Qwk	Not Reported
	Roactemra	S	Subcutaneous	162 Milligram, Qwk	Not Reported
	Spasmolyt	S	Unknown	30 Milligram, Qd	Not Reported
	Spasmolyt	S	Unknown	30 Milligram, Qd	Not Reported
	Spasmolyt	S	Unknown	15 Milligram, Qd	Not Reported
	Spasmolyt	S	Unknown	1 Dosage Form	Not Reported
	Omeprazole	S	Oral	1 Dosage Form, Bid	Not Reported
	Omeprazole	S	Oral	20 Milligram	Not Reported
	Ramipril	S	Oral	1 Dosage Form, Bid	Not Reported
	Ramipril	S	Unknown	5 Milligram, Qd	Not Reported
	Sildenafil	S	Unknown	60 Milligram, Daily Dose	Not Reported
	Pregabalin	S	Unknown	100 Milligram, Tid	Not Reported
	Pregabalin	S	Unknown	1 Dosage Form	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	16774890	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-219753			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Ranbaxy
	Ramipril			S	Unknown	5 Milligram		Ranbaxy
	Pregabalin			S	Unknown	100 Milligram, Tid		Sun
	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Astrazeneca
	Omeprazole			S	Unknown	20 Mg, Bid		Astrazeneca
	Volibris			S	Oral	30 Milligram, Qd		Not Reported

	Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1)	Not Reported
	Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1)	Not Reported
	Quensyl	S	Unknown	20 Mg Bid	Not Reported
	Eliquis	S	Unknown	2.5 Milligram, Bid	Not Reported
	Spasmolyt	S	Unknown	1 Df, Qd	Not Reported
	Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
	Spasmolyt	S	Unknown	15 Milligram	Not Reported
	Volibris	S	Oral	1 Dosage Form, Qd	Not Reported
	Ambrisentan	S	Unknown	1 Dosage Form, Qd	Not Reported
	Lyrica	S	Unknown	300 Milligram, Daily	Not Reported
	Eliquis	S	Unknown	2 Dosage Form, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	16972574	EXPEDITED (15-DAY)		DE, OT	CA-ABBVIE-19K-028-2978585-00		36 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis;	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported

Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Doxycycline Hyclate	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Simponi	C	Unknown	Not Reported
	Rituximab W/Urelumab	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17024269	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-GSH201908-001839			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Hydroxychloroquine			S	Unknown	20 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown	40 Mg, Bid (1 Df, Bid (1- 0 -1))		Concordia
	Ramipril			S	Oral	1 Dosage Form, Bid, (1 - 0 - 1)		Not Reported
	Ramipril			S	Unknown	5 Mg, Qd		Not Reported
	Pregabalin			S	Unknown	300 Mg, Tid		Not Reported
	Pregabalin			S	Unknown	1 Dosage Form, Tid		Not Reported
	Pregabalin			S		100 Mg		Not Reported
	Omeprazole			S	Oral	1 Dosage Form, Bid (1-0-1)		Not Reported
	Omeprazole			S	Oral	20 Mg, Bid		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Volibris			S	Unknown	30 Mg, Qd		Not Reported
	Volibris			S	Unknown	Unk		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd		Not Reported
	Spasmolyt			S	Unknown	1 Dosage Form, Qd		Not Reported

	Spasmolyt	S	Unknown	15 Mg, Qd	Not Reported
	Apixaban	S	Unknown	2.5 Mg, Bid	Not Reported
	Apixaban	S	Unknown	2 Dosage Form, Qd	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw, Solution For Injection In Pre-Filled Syringe	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Sildenafil Citrate	S	Unknown	60 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17182091	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019231676			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Cimzia (Certolizumab Pegol)			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Tocilizumab			S	Subcutaneous	Unk		Not Reported

Apo-Prednisone	S	Unknown	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram Solution	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	Solution	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram Solution	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil (Hydroxychloroquine)	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Subcutaneous	500 Milligram	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17422218	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-04558		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product	Etanercept			S	Subcutaneous			Not Reported

Administered; Drug Ineffective; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Etanercept	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Apo-Azathioprine	S	Unknown	Unknown	Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Azathioprine	S			Not Reported
	Celebrex	S	Unknown	Unknown	Not Reported
	Celebrex	S	Unknown		Not Reported
	Celecoxib	S	Unknown	Unknown	Not Reported
	Celecoxib	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Prednisone	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not	Powder For Solution	Not Reported

		otherwise specified)	Intravenous	
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown	Unknown	Not Reported
Altace	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Apo-Gabapentin	C	Oral		Not Reported
Atorvastatin Calcium	C	Oral		Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported
Cipralex (Escitalopram)	C	Unknown		Not Reported
Citalopram Hydrobromide	C	Unknown		Not Reported
Conjugated Estrogens	C	Unknown		Not Reported
Conjugated Estrogens	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Escitalopram	C	Unknown		Not Reported
Estrace	C	Unknown		Not Reported
Gabapentin	C	Unknown		Not Reported
Gabapentin	C	Oral		Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Hydromorphone Hydrochloride	C	Oral		Not Reported
Hydromorphone Hydrochloride	C	Oral		Not Reported
Mupirocin	C	Topical	Unknown	Not Reported
Pantoloc (Pantoprazole)	C	Unknown		Not Reported
Shark Liver Oil	C	Unknown	Unknown	Not Reported

Tapentadol Hydrochloride	C	Unknown			Not Reported
Taro-Mupirocin	C	Topical	Unknown		Not Reported
Tramadol Hydrochloride	C	Oral			Not Reported
Tramadol Hydrochloride	C				Not Reported
Tramacet	C	Oral			Not Reported
Tramacet	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17631825	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200337612			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Keratitis	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17643631	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-015943			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis; Dermatitis Bullous; Drug Reaction With Eosinophilia And Systemic Symptoms; Pemphigus; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Aciclovir			S	Unknown	Unk		Aurobindo
	Cefixime			S	Unknown	Unk		Aurobindo
	Ceftriaxone			S	Unknown	Unk		Aurobindo
	Fluconazole			S	Unknown	Unk		Aurobindo
	Gentamicin			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown	Unk		Aurobindo

Metronidazole	S	Unknown	Unk	Aurobindo
Paracetamol	S	Unknown	Unk	Aurobindo
Risperidone	S		Unk	Aurobindo
Terbinafine	S	Unknown	Unk	Aurobindo
Ampicillin;Sulbactam	S	Unknown	Unk	Not Reported
Ketoprofen	S	Unknown	Unk	Not Reported
Clarithromycin	S	Unknown	Unk	Not Reported
Aspirin	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Vancomycin	S	Unknown	Unk	Not Reported
Enoxaparin	S	Unknown	Unk	Not Reported
Ceftazidime	S	Unknown	Unk	Not Reported
Oxacillin	S	Unknown	Unk	Not Reported
Clindamycin	S	Unknown	Unk	Not Reported
Carbamazepine	S	Unknown	Unk	Not Reported
Phenytoin	S	Unknown	Unk	Not Reported
Phenobarbital	S	Unknown	Unk	Not Reported
Teicoplanin	S	Unknown	Unk	Not Reported
Rufinamide	S	Unknown	Unk	Not Reported
Cotrimoxazole	S	Unknown	Unk	Not Reported
Cisplatin	S	Unknown	Unk	Not Reported
Fluorouracil	S	Unknown	Unk	Not Reported
Asa	S	Unknown	Unk	Not Reported
Lithium	S	Unknown	Unk	Not Reported
Methylphenidate	S	Unknown	Unk	Not Reported
Acetylcysteine	S	Unknown	Unk	Not Reported
Ibuprofen	S	Unknown	Unk	Not Reported
Acetaminophen	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17647567	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200403521			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17647577	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200403510		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Cimzia			C	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Folic Acid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17648818	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2020061361		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug	Belimumab			S	Unknown	Unk		Glaxosmithkline

Ineffective; Off Label Use; Pyrexia; Systemic Lupus Erythematosus; Therapy Non-Responder	Belimumab	S	Unknown	Unk	Glaxosmithkline
	Belimumab	S	Unknown	Unk	Glaxosmithkline
	Tacrolimus	S	Unknown	Unk Unk, Qd	Glaxosmithkline
	Prednisone	S	Unknown	25 Mg, Qd	Not Reported
	Prednisone	S	Unknown	12.5 Mg, Qd	Not Reported
	Prednisone	S	Unknown	15 Mg, Qd	Not Reported
	Prednisone	S	Unknown	15 Mg, Qd	Not Reported
	Prednisone	S	Unknown	7.5 Mg, Qd	Not Reported
	Prednisone	S	Unknown	10 Mg, Qd	Not Reported
	Prednisone	S	Unknown	50 Mg, Qd	Not Reported
	Prednisone	S	Unknown	25 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S		400 Mg, Qd	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk, Qd	Not Reported
	Rituximab	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Unknown	Unk (Pulses)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17659064	EXPEDITED (15-DAY)		OT	TH-ROCHE-2577353		44 YR	Male	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Injection Site Extravasation; Intentional Product Use Issue; Off Label Use; Proteinuria	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg/Day		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lopinavir			S	Unknown			Not Reported
	Ritonavir			S	Unknown			Not Reported
	Favipiravir			S	Unknown			Not Reported
	Darunavir			S	Unknown			Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Piperacillin			S	Unknown			Not Reported

	Tazobactam	S	Unknown		Not Reported
	Vancomycin	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17662183	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002382			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hallucination, Visual	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	400 Mg, Qd		Concordia
	Temesta			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668607	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030971		65 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Desoximetasone			C	Unknown	10 Milligram, Qd		Not Reported
	Diclofenac			C	Unknown	100 Milligram, Qd		Not Reported
	Methotrexate			C	Unknown			Not Reported

Voltaren [Diclofenac Sodium]	C	Unknown	100 Milligram, Qd		Not Reported
Xeljanz	C	Unknown			Not Reported
Zostavax	C	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668861	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1720		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisone			S	Endocervical			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

	Prednisone Acetate		C	Unknown	Not Reported
	Tylenol		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668878	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1723			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Blister; Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Lipitor			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Dovobet			C	Unknown			Not Reported
	Flovent			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Multi Vitamins & Minerals			C	Unknown			Not Reported
	Omeprazole			C	Unknown			Not Reported
	Ventolin			C	Unknown			Not Reported
	Vitamin D2			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668879	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1721		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Endocervical			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668886	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1730			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Musculoskeletal Stiffness;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Uveitis				otherwise specified)	
	Aralen Hydrochloride		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Myochrysine		S	Intramuscular	Not Reported
	Plaquenil		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669411	EXPEDITED (15-DAY)		HO	GR-TEVA-2020-GR-1222919		56 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pyrexia; Urinary Tract Infection; Urinary Tract Pain	Ciclosporin			S	Oral	50 Mg, 2x/Day		Ivax
	Hydroxychloroquine Phosphate			S	Oral	200 Mg, 1x/Day		Not Reported
	Medrol			S	Oral	4 Mg, 1x/Day		Not Reported
	Thyrohormone			C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669462	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031059			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Codeine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	20 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669590	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096477			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Treatment Failure	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C		20 Mg, Qd		Not Reported
	Tylenol Arthritis Pain			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669591	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096338			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Fracture; Infection; Pneumonia	Arava			S	Oral			Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown			Sanofi
	Celecoxib			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Mg		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	1.0 Df, Qw		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669592	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096116			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Retinal Injury	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Humira			C				Not Reported
	Methotrexate			C		Unk		Not Reported
	Xeljanz			C				Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669596	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA096531		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure Congestive; Hypertensive Heart Disease; Peripheral Swelling; Therapeutic Response Changed	Plaquenil			S		200 Mg, Bid		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Arava			S	Oral	20 Mg		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669689	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2020M1037212		30 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulopathy; Herpes Simplex; Herpes Simplex Hepatitis; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported
	Acetaminophen			C	Unknown	6 Gram		Mylan
	Metronidazole			C	Oral			Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669899	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009850			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Exposure Via Breast Milk	Leflunomide			S	Transmammary	Unk		Apotex
	Hydroxychloroquine			S	Transmammary	Unk		Apotex
	Methotrexate			S	Transmammary	Unk		Not Reported
	Enbrel			S	Transmammary	Unk		Not Reported
	Certolizumab Pegol			S	Transmammary	Unk		Not Reported
	Prednisone			C	Transmammary	Unk		Not Reported
	Sulfasalazine			C	Transmammary	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17669916	DIRECT		DE				Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Torsade De Pointes	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S			1 DAY	Not Reported
	Azithromycin			S				Not Reported
	Azithromycin			S			2 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17670319	EXPEDITED (15-DAY)		DE	ES-FRESENIUS KABI-FK202003746		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sudden Death	Levofloxacin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Ritonavir/Lopinavir			S	Oral			Not Reported
	Enoxaparin Sodium			C	Subcutaneous			Not Reported
	Prednisone			C	Oral			Not Reported
	Ceftriaxone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17670426	EXPEDITED (15-DAY)		HO, OT	NL-TEVA-2020-NL-1222817		31 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Maternal Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Pre-Eclampsia; Premature Delivery	Sulfasalazine			S	Oral	2000 Milligram Daily;		Actavis
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Actavis
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Teva
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Teva
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Teva
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q2w		Not Reported
	Omeprazole			C	Oral	20 Milligram Daily;		Not Reported
	Novorapid			C	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17670440	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1223401		75 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Sudden Death	Levofloxacino (2791a)			S	Unknown			Teva
	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Mg		Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Lopinavir+Ritonavir			S	Oral	4 Dosage Forms Daily;		Not Reported
	Enoxaparina Sodica (2482so)			C	Subcutaneous	40 Mg		Not Reported
	Prednisona (886a)			C	Oral	20 Mg		Not Reported
	Ceftriaxona (501a)			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17670925	EXPEDITED (15-DAY)		DE, OT	ES-CIPLA LTD.-2020ES02594			Unknown	ESP

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

Sudden Death	Levofloxacin	S	Unknown	Unk	Cipla
	Hidroxicloroquina Sulfato	S	Oral	200 Milligram, Per Day	Not Reported
	Azitromicina	S	Oral	500 Milligram, Per Day	Not Reported
	Lopinavir/Ritonavir	S	Oral	2 Dosage Form, Bid	Not Reported
	Ceftriaxona [Ceftriaxone]	C	Unknown	Unk	Not Reported
	Enoxaparina Sodica	C	Subcutaneous	40 Milligram, Per Day	Not Reported
	Prednisona	C	Oral	20 Milligram, Per Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671067	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096278			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort;	Plaquenil			S				Sanofi
Alopecia; Contraindicated	Hydroxychloroquine Sulfate			S				Sanofi
Product Administered;	Arava			S				Sanofi
Fatigue; Glossodynia;	Cetirizine Hydrochloride			S				Not Reported
Hand Deformity; Pain;	Folic Acid			S				Not Reported
Pemphigus; Swelling;	Alendronate Sodium			S				Not Reported
Systemic Lupus	Methotrexate			S				Not Reported
Erythematosus; Wound	Prednisone			S				Not Reported
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671115	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096445			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Intolerance; Fatigue; Malaise	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Arava			S	Unknown			Sanofi
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Prednisone			S		1 Df, Qw		Not Reported
	Prevacid			C				Not Reported
	Risedronate Sodium			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671152	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223013		63 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rhabdomyolysis	Hidroxicloroquina (2143a)			S	Oral	2-5 Day: 200mg / 12h		Teva
	Hidroxicloroquina (2143a)			S	Oral	1 Day: 400mg / 12h, 2-5 Day: 200mg / 12h		Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671153	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223386		68 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	200mg/12h		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500mg/24h		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h		Not Reported

Ceftriaxona (501a)		S		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671318	EXPEDITED (15-DAY)		DS	CA-SAMSUNG BIOEPIS-SB-2020-12495			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672025	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200413067		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Liver Function Test Increased	Simponi			S	Subcutaneous			Janssen
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672031	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200413062			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Joint Swelling; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Plaquenil /00072603/			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672057	NON-EXPEDITED			US-CELGENEUS-USA-20200403202		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Otezla			S	Oral	60 Milligram		Celgene
	Plaquenil			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672078	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1221322			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Flutter	Hydroxychloroquine Sulfate Watson			S	Unknown			Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672447	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-12513			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Etanercept			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Single Use Pre-Filled Syringe Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported
	Azathioprine			C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17672893	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3363203-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Blister; Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Humira			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Lipitor			S	Oral			Not Reported
	Dovobet			C	Topical			Not Reported
	Folic Acid			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Flovent			C	Respiratory (inhalation)			Not Reported
	Ventolin			C	Respiratory (inhalation)			Not Reported
	Vitamin D2			C	Oral			Not Reported
	Multi Vitamin			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673591	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096533			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased; Pneumonitis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported

	Actemra	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Pneumococcal Vaccine Polysacch 23v	C	Unknown			Not Reported
	Prevnar 13	C	Intramuscular			Not Reported
	Varicella Zoster Vaccine Live	C	Unknown			Not Reported
	Xeljanz	C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673602	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030963		42 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; C-Reactive Protein Increased; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Orencia			S	Endocervical			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673612	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020153377			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Pfizer
	Etanercept			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673774	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202004002881			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Malaise; Systemic Lupus Erythematosus Rash	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17673830	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002619			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Inflammation; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674032	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-018904		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Tachyarrhythmia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Once A Day		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674037	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018903		63 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo

	Tocilizumab		S	Intravenous (not otherwise specified)	600 Milligram, 1 Total	Not Reported
	Dolquine		S	Oral	400 Milligram, Once A Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674055	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018905		64 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Dolquine			S	Other	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674074	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031130			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Orencia			S	Endocervical			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unk, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mefenamic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

	Tylenol		C	Unknown		Not Reported
	Prednisone		C	Oral	10 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17674075	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018907		28 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day		Aurobindo
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Ceftriaxone			S				Not Reported
	Azithromycin			S	Oral	500 Milligram, Once A Day		Not Reported
	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17675095	DIRECT	Y	DE			88 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Decreased; Pulmonary Embolism; Unresponsive To Stimuli	Hydroxychloroquine			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	12776522	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-024854		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qmo		Bristol Myers Squibb

Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Enbrel	S	Subcutaneous	50 Mg, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	4 Mg/Kg, Unk	Not Reported
	Actemra	S	Unknown	40 Milligram/Kilogram	Not Reported
	Actemra	S	Unknown	4 Milligram	Not Reported
	Arava	S	Oral	10 Mg, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
	Humira	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Cyclical	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Methotrexate	S	Unknown	25 Mg, Qwk	Not Reported
	Methotrexate	S	Unknown	250 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Mg, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Qmo	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	50 Milligram, Bid	Not Reported
	Prevacid	C	Unknown	30 Mg, Bid	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Prednisone	C	Unknown	50 Milligram, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	15396329	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180911207		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Rheumatoid Arthritis; Somnolence; Visual Impairment	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Tylenol			S	Unknown			Johnson And Johnson
	Paracetamol			S	Unknown			Johnson And Johnson
	Paracetamol			S	Unknown			Johnson And Johnson
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Unknown			Not Reported

Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Actemra	S	Subcutaneous	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Acetaminophen W/Codeine Phosphate	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported
Tylenol W/Codeine No. 3	C	Unknown	Not Reported
Celebrex	C	Oral	Not Reported
Hydromorphone Hydrochloride	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	15621514	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557370-00		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Sulfasalazine	S	Unknown	Not Reported
	Apo Hydroxyquine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	16844994	EXPEDITED (15-DAY)		OT	GR-PFIZER INC-2019378939		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Exemestane			S		Unk		Pfizer
	Lansoprazole			S	Unknown	Unk		Pfizer
	Ramipril			S	Unknown	Unk		Pfizer
	Prednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Dicumarol			S	Unknown	Unk		Not Reported
	Thyroxine			S	Unknown	Unk		Not Reported
	Thyroxine			S	Oral	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Metformin Hydrochloride			S		Unk		Not Reported

	Levothyroxine Sodium			S	Oral	Unk				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17180775	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019054476		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated; Contraindicated Product Administered; Decreased Appetite; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Headache; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Hypertension; Hypoaesthesia; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Malaise; Maternal Exposure During Pregnancy; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash;	Cimzia			S	Subcutaneous			Ucb
	Cimzia			S				Ucb
	Cetirizine Hydrochloride			S		10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S		10 Milligram		Ucb
	Cetirizine Hydrochloride			S				Ucb
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		400 Milligram, Once Daily (Qd)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	400 Milligram, Weekly (Qw)		Not Reported
	Simponi			S	Subcutaneous	50 Milligram, Monthly (Qm)		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S		Solution And Suspension For Injection In Pre-Filled Syringe		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Weekly (Qw)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Solution		Ucb
	Orencia			S		Unk		Not Reported

Rheumatic Fever; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S	Oral	5 Milligram, 2x/Week	Not Reported
	Apo Prednison	S			Not Reported
	Apo Prednison	S		Unk	Not Reported
	Arava	S	Oral		Not Reported
	Cortisone Acetate	S		25 Milligram	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S		0.5 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Methotrexate	S		20 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S		20 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine	S		400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S			Not Reported
	Pseudoephedrine Hcl	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
	Rituxan	S	Subcutaneous	Solution	Not Reported
	Salazopyrine	C	Oral	1 Gram, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Once Daily (Qd)	Not Reported
	Sulfathalidine	S			Not Reported

Orencia	S	Subcutaneous		Not Reported
Leflunomide	S	Oral		Not Reported
Hydroxychloroquine Phosphate	S		400 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Phosphate	S		400 Milligram, Once Daily (Qd)	Not Reported
Tocilizumab	S	Subcutaneous		Not Reported
Etanercept	S		Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
Winpred	S	Oral		Not Reported
Paracetamol	S			Not Reported
Stelara	S			Not Reported
Diclofenac Sodium	S			Not Reported
Topicort Lp	S	Subcutaneous	Unk	Not Reported
Topicort Lp	S	Oral		Not Reported
Sarilumab	S			Not Reported
Ustekinumab	S	Intravenous (not otherwise specified)	45 Milligram	Not Reported
Apo-Hydroxyquine	S			Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported
Otezla	S	Oral		Not Reported
Otezla	S	Oral		Not Reported
Reactine [Cetirizine Hydrochloride]	S			Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Desoximetasone	S	Oral		Not Reported
Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
Methotrexate	C	Subcutaneous		Not Reported
Methotrexate	C	Subcutaneous		Not Reported
Tofacitinib Citrate	C	Oral	5 Milligram, Weekly (Qw)	Not Reported

	Desoximetasone	C	Oral	25 Milligram, Weekly (Qw)	Not Reported
	Diclofenac	C		50 Milligram, Once Daily (Qd)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17302274	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA014510		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Leflunomide			S	Unknown	Unk		Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Prednisone			S	Unknown	Unk		Not Reported
	Pethidine Hydrochloride			S	Unknown	Unk		Sanofi
	Pethidine Hydrochloride			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	Unk Unk, Qw		Not Reported
	Metronidazole			S	Unknown	Unk		Sanofi
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Demerol			S	Unknown	Unk		Sanofi
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	400 Mg		Not Reported
	Bisoprolol Salt Not Specified			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	200 Mg		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd		Not Reported
	Erythromycin			S	Unknown	Unk		Sanofi
	Erythromycin			S	Unknown	Unk		Sanofi
	Erythromycin Estolate			S	Unknown	Unk		Not Reported

Levofloxacin	S	Unknown	Unk		Not Reported
Pregabalin	S	Unknown	Unk		Not Reported
Norfloxacin	S	Unknown	Unk		Not Reported
Plaquenil	S	Oral	400 Mg, Qd		Sanofi
Plaquenil	S	Oral	Unk		Sanofi
Arthrotec	S	Unknown	Unk		Not Reported
Levofloxacin Hemihydrate	S	Unknown	Unk		Not Reported
Diclofenac Sodium/Misoprostol	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	400 Mg		Not Reported
Methotrexate Sodium	S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17315940	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014237		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Pain; Synovitis	Leflunomide			S	Unknown	Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Naproxen			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	2 G		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown	Unk Unk, Qm		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

Arava	C	Oral	20 Mg, Qd		Not Reported
Risedronate	C	Oral	35 Mg, Qw		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17315972	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014485			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Product Use Issue; Rheumatoid Arthritis	Leflunomide			S	Unknown	20.0 Mg, Qd (20.0 Milligram 1 Every 1 Days)		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid (2 Every 1 Days)		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qw		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg (Every 2 Weeks)		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow (Once Every 2 Weeks)		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Wellbutrin			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17323512	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014590			Female	CAN

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

Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Unknown	20 Mg		Sanofi
	Plaquenil	S		200 Mg, 2 Every 1 Day		Sanofi
	Methotrexate	S		15 Mg, Qw		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S	Unknown			Sanofi
	Actemra	S	Unknown	567 Mg, Qm, 1 Every 4 Week		Not Reported
	Cimzia	S				Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous			Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Unknown			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Celebrex	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17332071	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-01520		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown	Unknown	Not Reported
	Alendronic Acid	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Codeine	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported

Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported

Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Myochrysine	S	Intramuscular	(Solution)	Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown (Powder For Solution Intravenous)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown (Powder For Solution Intravenous)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Azathioprine	S	Unknown	Unknown	Not Reported
Celebrex	S	Unknown	Unknown	Not Reported
Naproxen	S	Unknown	Unknown	Not Reported

Apo-Hydroxyquine	S	Unknown	Unknown		Not Reported
Ciclosporin	C	Unknown			Not Reported
Ciclosporin	C	Unknown			Not Reported
Prednisolone	C	Unknown			Not Reported
Prednisolone	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Prednisone	C	Unknown			Not Reported
Xeljanz	C	Oral			Not Reported
Xeljanz	C	Unknown			Not Reported
Xeljanz	C	Unknown			Not Reported
Xeljanz	C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17365657	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023782			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate			S				Sanofi
	Prednisone			S				Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Leflunomide			S	Oral			Sanofi
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S				Not Reported
	Methotrexate			S				Not Reported
	Arava			S				Sanofi
	Prednisone			S				Not Reported
	Sulfasalazine			S		500 Mg		Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported

	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17486747	EXPEDITED (15-DAY)		OT	IT-VELOXIS PHARMACEUTICALS-2020VELIT-000200		43 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Off Label Use	Envarsus			S	Unknown	Unk, Qd		Chiesi
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			S	Unknown	50 Mg Qd, Tapering Dose		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	25 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	15 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	10 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	7.5 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	12.5 Mg Qd, Dose Tapering		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported

Belimumab	S	Unknown	Unk		Not Reported
Immunoglobulin I.V	C		Unk		Not Reported
Rituximab	C		Unk		Not Reported
Methylprednisolone	C		Unk (Pulses)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17511082	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200240044			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Stelara			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17517037	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200243788			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Simponi			S	Subcutaneous			Janssen
	Stelara			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

	Cosentyx	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17553274	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019148132		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	100 Milligram		Not Reported
	Apo Prednison			S	Unknown	7 Milligram, Qd		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Celebrex			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	1 Milliliter, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	7 Milligram, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	7 Milligram, Qd		Not Reported

	Celecoxib	S	Unknown	Unk		Not Reported
	Celecoxib	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17558038	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318943		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Joint Swelling; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Pain; Rheumatic Fever; Rheumatoid Arthritis; Spinal Stenosis; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Unevaluable Event; Urinary Tract Infection	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported
	Topicort /00028604/			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Celebrex			C	Unknown			Not Reported
	Gold			C				Not Reported
	Morphine			C	Unknown			Not Reported
	Tofacitinib			C	Oral			Not Reported
	Acetaminophen W/Dextropropoxyphene			C				Not Reported
	Desoximetasone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17558095	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200316684		55 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Aspirin /00002701/			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported
	Remicade			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17567096	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318557		59 YR	Male	CAN

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

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Simponi	S	Subcutaneous	Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Actemra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Pantoprazole Sodium	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Zopiclone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17605620	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333278			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Ill-Defined Disorder; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Off	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported

Label Use	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Gold	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17605625	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333276		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity; Rash	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17605640	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333287		73 YR	Female	CAN

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

Pulmonary Toxicity; Rheumatoid Arthritis; Treatment Failure	Simponi		S	Subcutaneous	Janssen
	Simponi		S		Janssen
	Cimzia		S	Subcutaneous	Not Reported
	Enbrel		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Unknown	Not Reported
	Orencia		S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17605656	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332784		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported

	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituxan	S	Endocervical	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17648281	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200403508		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Arthralgia; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Simponi			S	Subcutaneous			Janssen
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Penicillamine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Amitriptyline Hydrochloride			C				Not Reported
	Doxycycline			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Tobramycin			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17651850	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200316464		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Simponi			S	Subcutaneous			Janssen
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol Arthritis Pain			C	Unknown			Not Reported
	Tylenol Arthritis Pain			C				Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17658993	EXPEDITED (15-DAY)		LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030043		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra	S	Unknown		Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown		Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown		Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S	Unknown		Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomida	S	Unknown	Unk	Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	10 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Unknown	Unk	Not Reported

Rituximab	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Oral	Unk Unk, Bid	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Lyrica	C	Unknown	Unk	Not Reported
Kineret	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17663375	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-018165		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	Unk		Not Reported
	Lasilix			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sufentanil			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Perfalgan			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Noradrenaline Tartrate Renaudin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Tazocilline			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Transipeg			C	Oral	Unk		Not Reported

	Potassium Chloride		C	Intravenous (not otherwise specified)	Unk	Not Reported
	Nimbex		C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17670489	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1222995		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis; Hyperbilirubinaemia; Hypocoagulable State	Hydroxychloroquine			S	Oral	400 Milligram Daily; 200 Mg/12h		Teva
	Kaletra			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	12440760	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-042673		70 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Adverse Event; Anaphylactic Reaction; Arthralgia; Arthropathy; Blood Glucose Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Lupus-Like Syndrome; Multiple Allergies; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Lyrica			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	1.5 Milligram, Bid		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Increased	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qwk	Not Reported
	Mycophenolate Mofetil Hydrochloride	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo Mycophenolate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Apo Hydroxyquine	S	Unknown		Not Reported
	Pregabalin	S	Oral		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Plaquenil S	S	Oral	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported
	Cellcept [Mycophenolate Mofetil]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Prednisone	S	Urethral	25 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	1 Dosage Form	Not Reported
	Celecoxib	S	Oral	200 Milligram, Bid	Not Reported
	Piroxicam	C	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Levothyroxine	C	Unknown		Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	15622445	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557344-00		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo Sulfasalazine			S	Unknown			Not Reported
	Apo Leflunomida			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Used Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Enteric Coated		Not Reported
	Abatacept			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Azathioprine	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Minocycline	C		Not Reported
	Penicillamine	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Tocilizumab	C		Not Reported
	Actemra	C		Not Reported
	Prednisolone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	15657201	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20181128756		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	16613478	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20190721988		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities;	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Stelara			S	Subcutaneous			Janssen
	Motrin			S	Oral			Johnson And Johnson
	Motrin			S	Oral			Johnson And Johnson
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S				Not Reported
	Apremilast			S				Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Sulfasalazine			S	Endocervical			Not Reported

Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Tongue Disorder; Ulcer	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported

Infliximab	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S		Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Codeine	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Alendronic Acid	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Ciclosporin	S	Unknown	Not Reported
Colchicine	C	Oral	Not Reported
Febuxostat	C	Unknown	Not Reported
Gravol	C	Unknown	Not Reported
Mogadon	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Uloric	C	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported
Oxycodone	C	Unknown	Not Reported
Nitrazepam	C	Oral	Not Reported
Folic Acid	C	Unknown	Not Reported

	Dexilant	C	Oral	Not Reported
	Prednisolone	C	Unknown	Not Reported
	Prednisolone	C	Unknown	Not Reported
	Benadryl	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	16697274	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019344315			Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Apixaban			S		2.5 Mg, Bid		Not Reported
	Apixaban			S	Unknown	2 Df, Qd		Not Reported
	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Pfizer
	Ramipril			S		5 Mg, Qd		Pfizer
	Lyrica			S	Unknown	100 Mg, Tid		Pfizer
	Lyrica			S	Unknown	1 Df, Tid (1 Df, 3x/Day (1 - 1- 1))		Pfizer
	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Not Reported
	Omeprazole			S	Oral	20 Mg, Bid (40mg/Day)		Not Reported
	Sildenafil Citrate			S	Unknown	60 Mg, Qd		Pfizer
	Quensyl			S	Unknown	20 Mg, Bid (40 Mg/Day)		Not Reported
	Quensyl			S		40 Mg, Bid (80mg/Day)		Not Reported
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Spasmolyt			S	Unknown	1 Df, Qd; 1 Number Of Units In The Interval: 1 Definition Of The Interval:		Not Reported

				Day	
	Spasmolyt	S	Unknown	30 Mg, Qd; Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv	Not Reported
	Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
	Spasmolyt	S	Unknown	15 Mg, Qd	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Ambrisentan	S	Oral	30 Milligram, Qd	Not Reported
	Ambrisentan	S	Oral	1 Df, Qd	Not Reported
	Ambrisentan	S	Unknown	30 Mg, Qd	Not Reported
	Ambrisentan	S		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	16740198	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-GER/GER/19/0113518			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Oedema Peripheral; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1);		Not Reported
	Ramipril			S				Not Reported
	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Not Reported
	Omeprazole			S		20 Mg, Bid		Not Reported
	Sildenafil			S	Unknown	60 Milligram, Daily Dose		Not Reported
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1-0-1)		Not Reported

Eliquis	S	Unknown	1 Df, Bid (1-0-1)		Not Reported
Spasmolyt	S		1 Df, Qd (1-0-1)		Not Reported
Spasmolyt	S	Unknown	30 Mg (0 -0 -1)		Not Reported
Ambrisentan	S	Unknown			Not Reported
Ambrisentan	S	Unknown	30 Milligram, Qd		Not Reported
Lyrica	S	Unknown	100 Milligram, Tid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17114842	EXPEDITED (15-DAY)		OT	DE-TORRENT-00015319			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ambrisentan			S	Unknown	1 Dosage Form, Qd		Unknown
	Apixaban			S		2.5 Milligram, Bid		Unknown
	Eliquis			S	Unknown	1 Df, Bid (1-0-1)		Unknown
	Lyrica			S	Unknown	100 Milligram, Tid Capsule, Hard		Unknown
	Omeprazole			S	Oral	1 Df,2x/Day (1-0 -1)		Not Reported
	Pregabalin			S	Unknown	1 Df, Tid, 3x/Day (11-1)		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1-0-1)		Unknown
	Ramipril			S	Oral	1 Df, Bid, 2x/Day (1-0-1)		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw Pre-Filled Syringe		Unknown
	Sildenafil			S	Unknown	60 Milligram, Daily Dose		Not Reported
	Spasmolyt			S	Unknown	1 Df, 15 (Unit Unspecified), Qd (1-0-0)		Unknown
	Volibris			S	Oral	30 Milligram, Qd		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17216520	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-107050		59 YR	Female	CAN

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

Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Alendronic Acid	S	Unknown	Unk	Aurobindo
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Unknown	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Once A Day	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported

	Sulfasalazine	S	Oral	1000 Milligram		Not Reported
	Sulfathalidine	S	Unknown	Unk		Not Reported
	Diclofenac	C	Unknown	Unk		Not Reported
	Salazopyrin	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17314617	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014285			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Qw		Sanofi
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Unknown	125 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Wellbutrin			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17386415	EXPEDITED (15-DAY)		OT	GR-EMD SERONO-E2B_90074536		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Pain; Chest Pain; Cough;	Metformin			S	Unknown	Unk		Not Reported

Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Thyroxin	S	Unknown	Unk		Not Reported
	Thyroxin	S	Oral	Unk		Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S		Unk		Not Reported
	Belimumab	S	Unknown	Unk		Not Reported
	Prednisolone	S	Unknown	Unk		Not Reported
	Azathioprine	S	Unknown	Unk		Not Reported
	Ramipril	S	Unknown	Unk		Not Reported
	Exemestane	S	Unknown	Unk		Not Reported
	Lansoprazole	S	Unknown	Unk		Not Reported
	Dicumarol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17402570	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542912			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported

	Xeljanz			C	Unknown					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17403255	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016019500			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol Ra			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S		5 Milligram		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate			S		5 Milligram Solution		Not Reported
	Orencia			S		750 Milligram		Not Reported
	Orencia			S		750 Milligram		Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
	Prednisone			C		50 Milligram, Once Daily (Qd)		Not Reported
	Isoniazid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17411075	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-03838		60 YR	Female	CAN

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

Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Infliximab	S	Unknown	Unknown	Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Arava	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Gold	S	Intramuscular	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Penicillamine	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Oral		Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown	Unknown	Not Reported
	Azathioprine Sodium	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Cyclophosphamide	C	Intravenous (not	Unknown	Not Reported

			otherwise specified)			
	Docusate Sodium	C	Oral			Not Reported
	Elavil	C	Unknown	Unknown		Not Reported
	Prednisone	C	Oral			Not Reported
	Sulfasalazine	C	Oral			Not Reported
	Sulfasalazine	C	Unknown	Unknown		Not Reported
	Tobramycin	C	Unknown			Not Reported
	Doxycycline	C	Oral	Unknown		Not Reported
	Xeljanz	C	Unknown	Unknown		Not Reported
	Elavil	C	Unknown	Unknown		Not Reported
	Wellbutrin	C	Unknown	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17535019	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1196886		62 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Hepatic Steatosis	Hydroxychloroquine			S	Unknown			Teva
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17578035	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009106			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Topical	Unk		Not Reported

Enbrel	S	Subcutaneous	Unk		Not Reported
Fosamax	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	40 Mg, Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Methotrexate Sodium	S	Unknown	Unk		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Reactin /00884302/	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Cimzia	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17583365	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025908		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported

Methotrexate	S	Oral	Unk		Not Reported
Methotrexate	S	Subcutaneous	Unk		Not Reported
Rituximab	S	Intravenous drip	2000 Milligram		Not Reported
Sulfasalazine	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	50 Milligram, 2 Every 1 Days		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17611349	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20151008546			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported

	Anakinra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Cortisone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17614338	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009150			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Levofloxacin			S	Unknown	Unk		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Benadryl /00000402/			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported

Methotrexate	S	Unknown	Unk		Not Reported
Plaquenil /00072602/	S	Unknown	Unk		Not Reported
Pms Azithromycin	S	Unknown	250 Mg, Qd		Not Reported
Procytox	S	Unknown	Unk		Not Reported
Simponi	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Ezetrol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17623465	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342100			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17628959	EXPEDITED (15-DAY)		OT	DE-ADVANZ PHARMA-202003002234			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dizziness; Hallucination; Headache; Nausea	Hydroxychloroquine			S	Unknown	1 Peice Daily, Film Coated Tablet		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17655678	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1221608		80 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Azithromycine Anhydre			S	Oral	250 Milligram		Not Reported
	Lasilix 20 Mg/2 Ml, Solution Injectable En Ampoule			S	Intravenous (not otherwise specified)	2 Dosage Forms		Not Reported
	Plaquenil			S	Oral			Not Reported
	Sufentanil			C	Intravenous (not otherwise specified)			Not Reported
	Perfalgan 10 Mg/Ml, Solution Pour Perfusion			C	Intravenous (not otherwise specified)			Not Reported
	Noradrenaline (Tartrate De)			C	Intravenous (not otherwise specified)			Not Reported
	Midazolam			C	Intravenous (not otherwise specified)			Not Reported
	Tazocilline 4 G/500 Mg, Poudre Pour Solution Pour Perfusion			C	Intravenous (not otherwise specified)	4 Dosage Forms		Not Reported
	Transipeg			C	Oral			Not Reported
	Potassium (Chlorure De)			C	Intravenous (not otherwise specified)			Not Reported
	Nimbex			C	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17656152	EXPEDITED (15-DAY)		CA, OT	FR-SA-2020SA091764			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amniotic Fluid Volume Increased; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Premature	Lovenox			S	Transplacental	1 Df, Qd		Sanofi
	Lovenox			S	Transplacental	Unk		Sanofi
	Plaquenil			S	Transplacental	400 Mg, Qd		Sanofi

Baby	Plaquenil	S	Transplacental	Unk	Sanofi
	Aspegic (Acetylsalicylate Lysine)	S	Transplacental	1 Df, Qd	Not Reported
	Aspegic (Acetylsalicylate Lysine)	S	Transplacental	Unk	Not Reported
	Econazole Nitrate	S	Transplacental	300 Mg, Qd	Not Reported
	Cortancyl	S	Transplacental	1 Df, Qd	Not Reported
	Cortancyl	S	Transplacental	Unk	Not Reported
	Imurel [Azathioprine]	S	Transplacental	150 Mg, Qd	Not Reported
	Imurel [Azathioprine]	S	Transplacental	Unk	Not Reported
	Econazole	C	Transplacental	300 Mg, Qd	Not Reported
	Econazole	C	Transplacental	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	13165412	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005507		62 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Methotrexate			S	Unknown	150 Milligram		Not Reported
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	13852964	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070668		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Osteoporosis; Pain; Rash; Synovitis	Orencia			S	Unknown	Unk Unk, Qmo		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Methotrexate [Methotrexate Sodium]			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Mg, Bid		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			C	Oral	20 Milligram, Qd		Not Reported
	Risedronate			C	Oral	35 Milligram, Qwk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	15751693	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		46 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Drug Intolerance; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Unevaluable Event; Vomiting	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Prednisone			S	Unknown	50 Milligram		Not Reported
	Prednisone			S	Oral	3 Mg, Qd		Not Reported
	Prednisone			S	Oral	25 Milligram, Qd		Not Reported
	Prednisone			S	Oral	50 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
	Apo-Prednisone			S	Unknown	50 Milligram		Not Reported
	Apo-Prednisone			S	Unknown	25 Milligram, Qd		Not Reported
	Apo-Prednisone			S	Oral	3 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Indocid [Indometacin]			S	Unknown	Unk		Not Reported
	Indometacin			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Qd		Not Reported
	Gold (198 Au) Colloidal			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Milligram, Qwk		Not Reported

	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Cymbalta	C	Unknown	30 Milligram, Qd	Not Reported
	Folic Acid Aventis	C	Oral	Unk Unk, Qwk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2020	17563464	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022239		3 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile	Orencia			S	Intravenous (not otherwise specified)	250 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Anakinra			S	Unknown	50 Milligram		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	1.5 Milligram, Qwk		Not Reported

Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	50 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter	Not Reported
	Naproxen	S	Unknown		Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Triamcinolone	S	Other	Unk	Not Reported
	Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Triamcinolone Hexacetonide	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	12769848	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076833			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Pain;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	500 Milligram		Not Reported

Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	Unk, Bid	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported

Cannabis Sativa	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Oxycodone	S	Unknown	10 Milligram	Not Reported
Oxycodone Hydrochloride	S	Unknown		Not Reported
Xeljanz	S	Oral	Unk, Q12h	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Ilaris	S	Subcutaneous	Unk	Not Reported
Ilaris	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Unknown		Not Reported
Oxyquinoline Sulfate	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Rituximab;Urelumab	C	Unknown	Unk	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Kineret	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	12913692	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091875		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intracardiac	8 Milligram/Kilogram		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Rituximab;Vorhyaluronidase Alfa			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown	Unk		Not Reported
	Premarin			C	Unknown	Unk		Not Reported
	Tenormin			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported
	Cymbalta			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Elavil [Amitriptyline Hydrochloride]			C	Unknown	Unk		Not Reported
	Imitrex [Sumatriptan]			C	Unknown	Unk		Not Reported
	Lyrica			C	Unknown	Unk		Not Reported

Hydrochlorothiazide	C	Unknown	Unk		Not Reported
Acetaminophen	C	Unknown	Unk		Not Reported
Sumatriptan Succinate	C	Unknown	Unk		Not Reported
Amitriptyline Hydrochloride	C	Unknown	Unk		Not Reported
Amitriptyline	C	Unknown			Not Reported
Sumatriptan	C	Unknown			Not Reported
Tofacitinib	C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	13772085	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091773			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Drug Ineffective; Foot Deformity; Hand Deformity; Intentional Product Use Issue; Joint Swelling; Leukopenia; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown	400 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Qd		Not Reported

Hydroxychloroquine	S	Unknown	400 Milligram, Qd		Not Reported
Apo-Hydroxyquine	S	Unknown	400 Milligram		Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd		Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid		Not Reported
Adalimumab	S	Subcutaneous	40 Milligram		Not Reported
Solu-Medrol	C	Intravenous (not otherwise specified)	Unk		Not Reported
Paracetamol	C	Unknown	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	15402622	EXPEDITED (15-DAY)		HO, OT	CO-ACTELION-A-CH2018-179017		63 YR	Female	COL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Anxiety; Arrhythmia; Asthenopia; Blood Creatinine Increased; Bronchitis; Cardiac Failure; Chest Discomfort; Chest Pain; Choking; Coagulation Time Prolonged; Coagulopathy; Constipation; Diarrhoea; Discomfort; Dizziness; Dyspnoea; Ear Disorder; Eye Disorder; Fall; Fatigue; Feeling Abnormal; Fibromyalgia; Flatulence; Fluid Retention; Gait Disturbance; General Physical Health Deterioration; Head	Tracleer			S	Oral	62.5 Mg, Bid		Actelion
	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Opsumit			S	Oral	10 Mg, Od		Actelion
	Opsumit			S	Oral	10 Mg, Od		Actelion
	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Riociguat			S	Unknown	Unk		Not Reported
	Hidroxicloroquina			S	Unknown			Not Reported
	Levetiracetam			S	Unknown			Not Reported
	Carvedilol			C				Not Reported

Discomfort; Headache; Hyponatraemia; Hypotension; Hysterectomy; Inflammation Of Wound; Intestinal Obstruction; Joint Swelling; Loss Of Control Of Legs; Malaise; Memory Impairment; Mitral Valve Calcification; Mitral Valve Disease; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Product Availability Issue; Pulmonary Artery Occlusion; Reflux Gastritis; Renal Disorder; Swelling Face; Swelling Of Eyelid; Syncope; Tremor; Vasodilatation; Walking Aid User

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	15635082	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105542		57 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cardiac Disorder; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown			Not Reported

Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Oxycodone	S	Unknown	10 Milligram	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported

Hydroxychloroquine	S	Unknown			Not Reported
Marijuana	S	Unknown	Unk		Not Reported
Leflunomide	S	Unknown	Unk		Not Reported
Leflunomide	S	Oral	Unk		Not Reported
Rituximab	C	Unknown	Unk		Not Reported
Urelumab	C	Unknown	Unk		Not Reported
Lyrica	C	Oral			Not Reported
Prednisone	C	Unknown	Unk Unk, Qd		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Cannabis Sativa	S	Unknown			Not Reported
Xeljanz	S	Oral	Unk, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17528005	EXPEDITED (15-DAY)		DS, HO, OT	NVSC2020CA067701		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac			S	Oral	1 Df		Novartis
	Diclofenac			S	Oral	2 Df, Qd		Novartis
	Diclofenac			S	Oral	75 Mg, Bid		Novartis
	Diclofenac			S	Oral	75 Mg, Bid		Novartis
	Diclofenac			S	Oral			Novartis
	Diclofenac			S	Oral	Unk, Qd		Novartis
	Diclofenac			S	Oral	Unk		Novartis
	Pantoprazole			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
	Voltaren Sr			S	Oral	2 Df, Qd (75 Mg)		Not Reported

Voltaren Sr	S	Oral	Unk		Not Reported
Diclofenac Potassium	S	Oral			Novartis
Cambia	S	Oral	Unk, Qd		Not Reported
Cambia	S	Oral	Unk		Not Reported
Cambia	S	Unknown	75 Mg, Bid		Not Reported
Sulfasalazine	S	Oral	2 Df, Qd (1 Gram)		Not Reported
Sulfasalazine	S	Unknown	1 Df, Qd (500 Mg)		Not Reported
Pantoprazole Magnesium	S	Unknown	Unk		Not Reported
Plaquenil	S	Oral	1 Df, Qd		Not Reported
Synthyroid	S	Unknown	Unk		Not Reported
Xeljanz	S	Oral	2 Df, Qd		Not Reported
Gold	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17560345	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200309909			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor	Stelara			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Janssen
	Remicade			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Johnson And Johnson
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Johnson And Johnson
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported

Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Cortisone Acetate	S			Not Reported
	Desoximetasone	S	Unknown	And Oral	Not Reported
	Diclofenac	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	Unknown For 5.0 Mg, Through Oral 25.0 Mg,	Not Reported
	Folic Acid	S	Subcutaneous		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous	Unknown For 5.0 Mg, Through Oral 25.0 Mg,	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sarilumab	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfathalidine	S	Unknown		Not Reported
	Topicort /00370301/	S	Subcutaneous		Not Reported
	Topicort /00370301/	S	Topical		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17584672	EXPEDITED (15-DAY)		OT	NVSC2020US083168			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coeliac Disease; Gastrointestinal Pain; Joint Swelling	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17595157	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020012294			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia			S	Subcutaneous	Unk		Ucb
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cortisone Acetate			S				Not Reported
	Cortisone Acetate			S		25 Milligram		Not Reported
	Desoximetasone			S	Oral	And Oral		Not Reported
	Diclofenac			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S		5 Milligram		Not Reported
	Folic Acid			S	Oral	25 Milligram		Not Reported
	Fosamax			S	Oral			Not Reported
	Fosamax			S	Oral			Not Reported

Humira	S	Subcutaneous	4 Milligram		Ucb
Leflunomide	S		Unk		Not Reported
Methotrexate	S	Oral	25 Milligram		Not Reported
Orencia	S	Subcutaneous			Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S		400 Milligram, Once Daily (Qd)		Not Reported
Pseudoephedrine Hcl	S				Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sarilumab	S				Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)		Not Reported
Sulfathalidine	S		Unk		Not Reported
Topicort [Desoximetasone]	S	Subcutaneous	Unk		Not Reported
Topicort [Desoximetasone]	S	Topical	Unk		Not Reported
Xeljanz	S		5 Milligram, 2x/Day (Bid)		Not Reported
Xeljanz	S		5 Milligram		Not Reported
Hydroxychloroquine Sulfate	S				Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk		Not Reported
Apo-Hydroxyquine	S		Unk		Not Reported
Apo-Prednisone	S		Unk		Not Reported
Arava	S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17597328	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009074		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Breast Cancer; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache;	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Hydroxychloroquine			S	Oral	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex

Infection; Joint Swelling; Loss Of Consciousness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Apo-Leflunomide	S	Unknown	20 Mg, Unk	Apotex
	Leflunomide	S	Unknown	10 Mg, Unk	Apotex
	Leflunomide	S	Oral	20 Mg, Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	50 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	25 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	15 Mg, Qd	Not Reported
	Methotrexate	S	Endocervical	25 Mg, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	50 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Meloxicam	C	Unknown	Unk	Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2020	17652112	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1218243		51 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ascites; Atrioventricular Block First Degree; Cardiac Failure; Cardiomyopathy; Diastolic Dysfunction; Fluid Overload; Left Ventricular	Hydroxychloroquine			S	Unknown	Initial Dosage Not Stated; Tit		Teva
	Hydroxychloroquine			S	Unknown	400 Milligram Daily; Rated To 200mg Twice Daily In The First Year		Teva

Dysfunction; Right Ventricular Dysfunction; Toxicity To Various Agents	Prednisone		C	Unknown	Not Reported
	Rituximab		C	Other	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	12769487	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-015683			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Increased; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Femur Fracture; Gait Disturbance; Gastric Disorder; Glycosylated Haemoglobin Increased; Heart Rate Increased; Hepatic Enzyme Increased; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Lymphocyte Count Increased; Malaise; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Nausea; Nephrolithiasis; Neutrophil Count Increased; Osteopenia; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Product Use Issue;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown	200 Milligram		Bristol Myers Squibb
	Tylenol			S	Unknown	As Needed		Not Reported
	Enbrel			S	Unknown	50 Mg, Qwk(Loe)		Not Reported
	Enbrel			S	Unknown	40 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	2000 Mg(Intolerance)		Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	800 Milligram		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown	325 Milligram		Not Reported
	Acetaminophen			S	Unknown	Unk		Not Reported
	Apo Hydro			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	200 Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

Pyrexia; Rash; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Somnolence; Synovitis; Therapeutic Product Effect Incomplete; Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	200 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, 1 Every 24 Hours	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	200 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	5 Unit	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Acetaminophen	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
	Doxycycline	S	Unknown	100 Milligram, Bid	Not Reported
	Acetaminophen And Codeine Phosphate	S	Unknown	Unk	Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown	20 Nanogram	Not Reported
	Diphenhydramine Hydrochloride;Paracetamol	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	25 Dosage Form	Not Reported

Methotrexate	S	Unknown	Unk, Qwk		Not Reported
Meloxicam	C	Unknown			Not Reported
Synthroid	C	Unknown			Not Reported
Tylenol W/Codeine	C	Unknown			Not Reported
Celebrex	C	Oral	200 Mg, Bid		Not Reported
Hydromorphone Hydrochloride	C	Unknown			Not Reported
Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
Celecoxib	C	Unknown			Not Reported
Codeine	C	Unknown			Not Reported
Leflunomide	C	Unknown	20 Milligram, 2 Every 1 Day		Not Reported
Diphenhydramine	C	Oral	50 Milligram		Not Reported
Glyburide (Micronized)	C	Unknown	Unk		Not Reported
Hydrochlorothiazide	C	Unknown	Unk		Not Reported
Lipitor	C	Unknown			Not Reported
Metormin	C	Unknown			Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram		Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown	Unk		Not Reported
Ramipril	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	12913728	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091701			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoaesthesia; Infection; Nausea; Nephrolithiasis;	Orencia			S	Intravenous (not otherwise specified)	40 Milligram		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk, 152.0 Days		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk, 122		Not Reported

Nerve Injury; Neutropenia; Off Label Use; Osteoarthritis; Pain In Extremity; Paraesthesia; Product Use Issue; Pulmonary Congestion; Synovitis; White Blood Cell Count Decreased					Days	
	Humira		S	Subcutaneous	40 Milligram, 2 Every One Week	Not Reported
	Hydroxychloroquine		S	Oral	400 Milligram	Not Reported
	Methotrexate		S	Subcutaneous	Unk, 580.0 Days	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan		S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]		S	Oral	400 Milligram, 580.0 Days	Not Reported
	Apo-Hydroxyquine		S	Oral	400 Milligram	Not Reported
	Methotrexate Sodium		S	Subcutaneous	Unk	Not Reported
	Methotrexate		S	Oral	Unk	Not Reported
	Naprosyn E		S	Unknown	Unk	Not Reported
	Prednisone		S	Unknown	Unk	Not Reported
	Simponi		S	Subcutaneous	Unk	Not Reported
	Rituximab		S	Intravenous (not otherwise specified)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	12914292	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092847		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Arthropathy; Arthropathy; Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis;	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4mo		Bristol Myers Squibb

Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
	Anakinra	S	Subcutaneous	100 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	Unk Unk, Qwk	Not Reported
	Humira	S	Unknown	40 Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12.5 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Q2wk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	12.5 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Cyclical	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk,Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Day	Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Time In A Week	Not Reported
	Xeljanz	C	Unknown	Unk Unk, Bid	Not Reported
	Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	13153195	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005339			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Bone Disorder; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Pain; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tenosynovitis; Treatment Failure; Urticaria	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Rocuronium			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Not Reported
	Pencillin			S	Unknown	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported

Hydroxychloroquine Sulfate	S	Oral	Unk		Not Reported
Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk		Not Reported
Rocuronium Bromide	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Prednisone	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	13182370	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-1856140-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naproxen			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Prednisone Teva			S	Oral			Not Reported
	Plaquenil Sulfate			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported

	Hydroxychloroquine	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	15680209	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574019-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Celecoxib			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	15932044	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2651975-00		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthralgia; Blood	Humira			S	Subcutaneous			Not Reported

Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Folic Acid	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S		Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16396768	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2809469-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not			Not Reported

					otherwise specified)					
	Prednisone			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16841034	EXPEDITED (15-DAY)		OT	GR-BAUSCH-BL-2019-026015		59 YR	Female	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hyperparathyroidism Secondary; Osteoporosis; Rib Fracture; Upper Respiratory Tract Infection	Ramipril			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Bausch And Lomb
	Metformin Hydrochloride			S	Unknown			Santarus
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lansoprazole			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Exemestane			S	Unknown			Not Reported
	Thyroxine			S	Oral			Not Reported
	Thyroxine			S	Unknown			Not Reported
	Dicumarol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	16886720	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2946845-00		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Sulfathalidine			S	Oral			Not Reported

Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Cortisone	S	Topical		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown	Powder For Infusion	Not Reported
	Cetirizine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Methotrexaat	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Pre-Filled Syringe	Not Reported
	Arava	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine	S	Unknown		Not Reported
	Topicort (Hydrocortisone Acetate)	S	Cutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported

Desoximetasone	S	Oral	Not Reported
Diclofenac	S	Ophthalmic	Not Reported
Alendronate Sodium	S	Oral	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Golimumab	S	Unknown	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Stelara	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Acetaminophen	S	Unknown	Not Reported
Atasol	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17146486	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191211370			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Liver Injury; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Psoriatic	Reactine (Cetirizine Dihydrochloride)			S	Unknown			Johnson And Johnson
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S	Unknown			Johnson And Johnson
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi Iv			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported

Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Fosamax	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Calcium /00060701/	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Quetiapine	C	Unknown	Not Reported
	Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17260297	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017687			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Dorzolamide ,Timolol			S	Unknown	1 Df, Bid		Apotex
	Dorzolamide ,Timolol			S	Unknown	Unk Unk, Bid		Apotex
	Ramipril			S	Oral	Unk, Qd		Apotex
	Ramipril			S	Oral	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Levothyroxine			S	Unknown	1 Df, Unk		Not Reported
	Levothyroxine			S	Unknown	Unk, Qd		Not Reported
	Tylenol /00020001/			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Endocervical	400 Mg, Qd		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Dorzolamide Hydrochloride W/Timolol Maleate			C	Ophthalmic	Unk, Bid		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C	Unknown	One Once A Day		Not Reported
	Prednisone			C	Unknown	7 Mg, Qd		Not Reported

	Ramipril		C	Unknown	One Once A Day	Not Reported
	Tylenol No.2		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17261745	EXPEDITED (15-DAY)		OT	IL-GLAXOSMITHKLINE-IL2019EME238237			Male	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Benlysta			S		Unk		Glaxosmithkline
	Prednisone			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Clexane			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17332504	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004133		67 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown	Unk, Bid		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qwk		Not Reported
	Estrogel			C	Unknown	0.6 Percent, Tid		Not Reported
	Furosemide			C	Unknown	40 Milligram, Qd		Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram, Qd		Not Reported
	Valsartan			C	Unknown	320 Milligram, Qd		Not Reported

Xalatan	C	Unknown	50 Microgram, Qd		Not Reported
Zingiber Officinale	C	Unknown	500 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17517039	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200243785			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Liver Function Test Increased; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Uveitis	Stelara			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Naprosyn /00256201/			S	Unknown			Not Reported
	Piroxicam			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Plaquenil /00072602/	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Tocilizumab	S	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Codeine	C	Subcutaneous	Not Reported
Imuran /00001501/	C	Subcutaneous	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17577763	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329927		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Back Injury; Back Pain; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Proteinuria; Rheumatoid	Simponi			S	Subcutaneous			Janssen
	Arava			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Penicillamine			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Azathioprine			C				Not Reported
	Cyclophosphamide			C				Not Reported
	Docusate Sodium			C				Not Reported
	Doxycycline			C	Oral			Not Reported

Arthritis; Swelling; Treatment Failure; Vasculitis	Elavil /00002202/	C	Unknown	Not Reported
	Sulfasalazine	C	Oral	Not Reported
	Tobramycin	C	Intraocular	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17579767	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327866		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Headache; Hepatotoxicity; Insomnia; Joint Swelling; Memory Impairment; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported
	Anakinra			S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported

	Desoximetasone	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Insulin	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17579770	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327863		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Constipation; Diarrhoea; Dizziness; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Hypersensitivity; Insomnia; Iodine Allergy; Nausea; Oedema; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis; Synovitis; Vomiting	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Venlafaxine			C	Oral			Not Reported
	Folic Acid			C				Not Reported
	M-Eslon			C	Unknown			Not Reported
	Morphine			C				Not Reported
	Morphine Sulfate			C	Unknown			Not Reported
	Statex			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Naprosyn /00256201/			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17579772	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327858		39 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17579773	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327868		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Actonel			S				Not Reported
	Celebrex			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported

Incomplete; Treatment Failure	Prednisone	S	Unknown		Not Reported
	Prolia	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Minims Prednisolone Sodium Phosphate	S	Ophthalmic	0.5%	Not Reported
	Arava	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Cyclobenzaprine	C			Not Reported
	Desoximetasone	C			Not Reported
	Prednisone Acetate	C			Not Reported
	Tylenol /00020001/	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17605649	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332785		51 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankylosing Spondylitis; Arthralgia; Arthropathy; Drug Intolerance; Joint Swelling; Knee Arthroplasty; Therapeutic Product Effect Decreased; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S				Not Reported
	Xeljanz			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17605713	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332775		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Ankle Fracture; Contraindicated Product Administered; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Swelling; Malaise; Nausea; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Unevaluable Event; Vomiting	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	For 3 Years		Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	11 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	4 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Codeine Phosphate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Pregabalin			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17616081	EXPEDITED (15-DAY)		DE, HO	BR-ADVANZ PHARMA-202003002042			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Corona Virus Infection; Drug Ineffective; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623454	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340457		63 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Decreased; Weight Increased	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Asacol			S	Unknown			Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gliclazide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported

Acetaminophen	C	Oral	Not Reported
Atacand Plus	C	Unknown	Not Reported
Bisoprolol Fumarate	C	Unknown	Not Reported
Depo-Medrol	C	Intra-articular	Not Reported
Diphenhydramine	C	Oral	Not Reported
Ebastine	C	Unknown	Not Reported
Ferrous Gluconate	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
Rosuvastatin Calcium	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623463	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342096		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Malaise; Nausea; Stress	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1.0 Dosage Forms		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Plaquenil /00072602/	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Advil /00044201/	C	Unknown	Not Reported
Prednisone	C	Oral	Not Reported
Prednisone	C	Oral	Not Reported
Tylenol /00020001/	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623466	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340460		48 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Hypertension; Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Arava	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623532	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340124		64 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Cyclobenzaprine			C	Oral			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Leflunomide			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone Acetate			C	Unknown			Not Reported

	Tylenol /00020001/		C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623533	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340125		59 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Asthenia; Back Pain; Bursitis; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Dry Mouth; Facet Joint Syndrome; Headache; Inflammation; Joint Range Of Motion Decreased; Joint Swelling; Lip Dry; Liver Disorder; Lung Disorder; Muscle Spasms; Musculoskeletal Pain; Musculoskeletal Stiffness; Night Sweats; Obesity; Oedema; Oedema Peripheral; Off Label Use; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Peripheral Swelling; Peripheral Venous Disease; Red Blood Cell Sedimentation Rate Abnormal; Rheumatic Fever; Swelling; Synovitis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Asa			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetaminophen			C				Not Reported
	Ultracet			C				Not Reported
	Calcite D			C	Unknown			Not Reported
	Citalopram			C				Not Reported
	Domperidone			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Gabapentin			C				Not Reported
	Gliclazide			C	Unknown			Not Reported
	Lipitor			C				Not Reported
	Nifedipine			C				Not Reported
	Pantoloc /01263204/			C	Unknown			Not Reported
	Pantoprazole			C				Not Reported
	Risedronate			C	Unknown			Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

	Synthroid		C			Not Reported
	Tylenol /00020001/		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623537	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340129		76 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Limb Discomfort; Musculoskeletal Discomfort; Off Label Use; Pain; Pharyngeal Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Penicilline G /00000901/			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623540	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340132			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Pulmonary Toxicity;	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17623542	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200340452		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Fine Motor Skill Dysfunction; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17666231	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029672		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17672252	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200413057		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Contraindicated Product Administered; Drug Ineffective	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S				Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17672253	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200411530		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Chloroquine Diphosphate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

	Xeljanz	S	Oral	Not Reported
	Erythromycin	C	Unknown	Not Reported
	Morphine	C	Topical	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	11607841	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-JNJFOC-20150923280		41 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adjustment Disorder With Depressed Mood; Adverse Event; Alopecia; Amnesia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Breast Cancer Stage Iii; Condition Aggravated; Contraindicated Product Administered; Delirium; Depression; Diarrhoea; Disability; Discomfort; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Gait Disturbance; General Physical Health Deterioration; Glossodynia; Glossodynia; Grip Strength Decreased; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty;	Simponi			S	Subcutaneous			Janssen
	Stelara			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Zyrtec			S	Oral			Johnson And Johnson
	Zyrtec			S	Unknown			Johnson And Johnson
	Reactine (Cetirizine Dihydrochloride)			S	Oral			Johnson And Johnson
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

Hypersensitivity; Infection; Infusion Related Reaction; Joint Range Of Motion Decreased; Joint Swelling; Knee Arthroplasty; Memory Impairment; Mobility Decreased; Muscular Weakness; Off Label Use; Pain; Pain In Extremity; Pemphigus; Pericarditis; Peripheral Swelling; Product Use In Unapproved Indication; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Seronegative Arthritis; Sleep Disorder; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Treatment Noncompliance; Type 2 Diabetes Mellitus; Walking Aid User; Weight Decreased; Wound; Wound Infection	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Sunconjunctival		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therpay Duration 11 Monts	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Fosamax	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution For Injection/Infusion	Not Reported
	Rituxan	S	Intravesical	Solution For Injection/Infusion	Not Reported
	Phthalylsulfathiazole	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Subcutaneous		Not Reported
	Cortisone	S	Topical		Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Urethral		Not Reported

Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Not Reported
Topicort (Hydrocortisone Acetate)	S	Cutaneous	Not Reported
Topicort (Hydrocortisone Acetate)	S	Oral	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Acetaminophen	S	Oral	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Paracetamol	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Cosentyx	S		Not Reported
Salazopyrin	C	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported
Atasol	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	12912114	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20160308952			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Conjunctivitis; Fatigue; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Infection	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Amlodipine Besilate			C				Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Mavik			C	Unknown			Not Reported
	Olopatadine Hydrochloride			C	Ophthalmic			Not Reported
	Prednisone			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	12914315	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-093127		58 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase	Orencia			S	Intravenous (not otherwise specified)	760 Milligram, Qwk		Bristol Myers Squibb

Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Gastric Disorder; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Product Effect	Orencia	S	Unknown	780 Milligram, Qwk	Bristol Myers Squibb
	Orencia	S	Subcutaneous	Unk	Bristol Myers Squibb
	Tocilizumab	S	Unknown	360 Milligram, Q4wk	Not Reported
	Tocilizumab	S	Unknown	680 Milligram, Q4wk	Not Reported
	Tocilizumab	S	Unknown	360 Milligram, Qwk	Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Tocilizumab	S	Unknown	380 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Q4wk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Q4wk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Q4wk	Not Reported
	Methotrexate	S	Unknown	17.5 Milligram, Q4wk	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Q2wk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Q2wk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported

Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Tongue Disorder; Ulcer	Methotrexate	S	Unknown	10 Milligram, Q4wk	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	380 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	500 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Q2wk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	360 Milligram, Qmo	Not Reported
	Hydroxychloroquine	S	Unknown	680 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Q2wk	Not Reported
	Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
	Myochrysine	S	Unknown	10 Milligram	Not Reported
	Myochrysine	S	Unknown	50 Milligram, Qmo	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram, Q4wk	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported
	Sulfasalazine	S	Endocervical	500 Milligram	Not Reported

Sulfasalazine	S	Endocervical	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Rituxan	S	Unknown	1000 Milligram, Bid	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Cyclosporin	C	Unknown	Unk	Not Reported
Cyclosporin	C	Unknown	150 Milligram, Qd	Not Reported
Actemra	S	Unknown	680 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	360 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	2.68 Milligram, Q4wk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Milligram, Qmo	Not Reported
Simponi	S	Unknown	360 Milligram, Qmo	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Ibuprofen	S	Oral	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
Apremilast	S	Unknown		Not Reported
Apremilast	S	Unknown		Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Ibuprofen	S	Oral	600 Milligram, Qd	Not Reported
Infliximab	S	Oral	Unk	Not Reported
Motrin [Ibuprofen]	S	Oral	600 Milligram, Qd	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Colchicine	C	Unknown	Unk	Not Reported
Dexilant	C	Oral	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported

Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Uloric	C	Oral	80 Milligram, Bid	Not Reported
Prednisolone	C	Unknown	10 Milligram	Not Reported
Prednisolone	C	Unknown	20 Milligram	Not Reported
Prednisone	C	Unknown	20 Milligram	Not Reported
Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Alendronate	C	Unknown	70 Milligram, Qwk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Etanercept	S	Unknown	25 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	14908110	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP013244			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral	7.5 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
	Mobicox			S	Oral	7.5 Mg, Qd		Not Reported
	Actemra			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Q.Wk.		Not Reported

Enbrel	S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Methotrexate Sodium	S	Oral	20 Mg, Q.Wk.		Not Reported
Plaquenil /00072602/	S	Unknown			Not Reported
Sulfasalazine	C	Oral	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15623907	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2554647-00		79 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Vorhyaluronidase Alfa			S	Intravenous (not otherwise specified)			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported

	Cymbalta	C	Unknown	Not Reported
	Elavil	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Sumatriptan Succinate	C	Unknown	Not Reported
	Imitrex	C	Unknown	Not Reported
	Sumatriptan	C	Unknown	Not Reported
	Amitriptyline	C		Not Reported
	Tofacitinib	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15676976	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573583-00		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Infection; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Actonel	S	Unknown	Not Reported
	Apo Risedronate	S	Unknown	Not Reported
	Apo Risedronate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Risedronate	S	Unknown	Not Reported
	Apo Risedronate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	15801087	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2617003-00		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S				Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

	Xeljanz	S	Oral			Not Reported
	Leucovorin	S	Unknown			Not Reported
	Hydroxychloroquine Sulfate	S	Oral			Not Reported
	Leflunomide	S	Oral			Not Reported
	Prednisone	S	Unknown	2 Dosage Forms		Not Reported
	Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	16080823	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013796		54 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; No Adverse Event	Celecoxib Capsules			S	Oral	Unk		Aurobindo
	Celecoxib			S	Unknown	Unk		Aurobindo
	Celecoxib			S				Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	100 Milligram		Not Reported
	Prednisone			S	Unknown	7 Milligram, Once A Day		Not Reported
	Apo-Prednisone			S	Unknown	7 Milligram, Once A Day		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S				Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	1 Milliliter, Every Week		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

	Simponi		S	Unknown	Unk	Not Reported
	Celebrex		S	Unknown	Unk	Not Reported
	Cimzia		S	Unknown	Unk	Not Reported
	Humira		S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate		S	Oral	Unk	Not Reported
	Remicade		S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	16710769	EXPEDITED (15-DAY)		OT	DE-ASTRAZENECA-2019SF17234			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Omeprazole			S	Oral			Not Reported
	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Not Reported
	Ramipril			S	Oral			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Oral			Not Reported
	Volibris			S	Oral			Not Reported
	Eliquis			S	Unknown			Not Reported
	Eliquis			S	Unknown			Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval		Not Reported
	Quensyl			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported

	Sildenafil Citrate	S	Unknown		Not Reported
	Roactemra	S	Subcutaneous		Not Reported
	Roactemra	S	Subcutaneous		Not Reported
	Spasmolyt	S	Unknown	30 Mg, Qd; Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Int...	Not Reported
	Spasmolyt	S	Unknown	1 Df, Qd; 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day	Not Reported
	Spasmolyt	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17157342	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053627			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Liver Injury; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Cimzia			S	Subcutaneous	Unk		Ucb
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Actemra			S				Not Reported
	Arava			S		Unk		Not Reported
	Arava			S	Unknown			Not Reported
	Diclofenac Sodium			S				Not Reported
	Diclofenac Sodium			S		Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S		Unk		Not Reported

Fosamax	S	Unknown		Not Reported
Folic Acid	S			Not Reported
Folic Acid	S		1 Milligram	Not Reported
Humira	S	Subcutaneous	Solution	Ucb
Hydroxychloroquine Sulfate	S			Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Methotrexate	S		Solution	Not Reported
Methotrexate	S		Unk	Not Reported
Methotrexate	S		Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S			Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S			Not Reported
Prednisone	S		Unk	Not Reported
Prednisone	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Etanercept	S	Subcutaneous		Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown		Not Reported
Desoximetasone	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Cosentyx	S	Unknown		Not Reported

Calcium /00060701/	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Quetiapine	C	Unknown	Not Reported
Ramipril	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17314630	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014338			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava			S	Oral	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg, Qw		Sanofi
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Plaquenil			S	Oral	200 Mg (2 Every 1 Days)		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C		Unk		Not Reported
	Folic Acid			C	Oral	5 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17531498	EXPEDITED (15-DAY)		DS, HO, OT	CA-GLAXOSMITHKLINE-CA2020044221		68 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling;	Diclofenac			S	Oral	1 Df		Glaxosmithkline
	Diclofenac			S	Oral	2 Df, Qd		Glaxosmithkline

Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac	S	Oral	75 Mg, Bid	Glaxosmithkline
	Diclofenac	S	Oral	Unk	Glaxosmithkline
	Diclofenac	S	Oral	Unk, Qd	Glaxosmithkline
	Diclofenac	S	Oral	Unk	Glaxosmithkline
	Diclofenac Potassium	S	Oral	Unk	Glaxosmithkline
	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Voltaren Sr	S	Oral	2 Df, Qd (75 Mg)	Glaxosmithkline
	Voltaren Sr	S	Oral	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	Unk	Glaxosmithkline
	Cambia	S	Oral	Unk, Qd	Glaxosmithkline
	Cambia	S	Oral	Unk	Glaxosmithkline
	Cambia	S	Unknown	75 Mg, Bid	Glaxosmithkline
	Lisinopril	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	1 Df, Qw	Not Reported
	Sulfasalazine	S	Oral	2 Df, Qd (1 Gram)	Not Reported
	Sulfasalazine	S	Unknown	1 Df, Qd (500 Mg)	Not Reported
	Plaquenil	S	Oral	1 Df, Qd	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	2 Df, Qd	Not Reported
	Gold	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17664343	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009853			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Condition Aggravated;	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex

Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Treatment Failure; Vomiting	Leflunomide		S	Unknown	20 Mg, Qd	Apotex
	Infliximab		S	Unknown	Unk	Not Reported
	Orencia		S	Unknown	Unk	Not Reported
	Enbrel		S	Unknown	Unk	Not Reported
	Morphine		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17666251	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009862		63 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance	Cyclosporine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S				Apotex
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Neoral			S	Oral	Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg, Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Xeljanz			C	Unknown	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17668617	EXPEDITED (15-DAY)		LT, OT	FR-ADVANZ PHARMA-202003002364			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alkalosis; Deep Vein Thrombosis; Haemoglobin Decreased; Hyperglycaemia; Off Label Use; Overdose; Oxygen Saturation Decreased; Vascular Device Infection	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		1200 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd Film-Coated Tablet		Concordia
	Lovenox			S	Subcutaneous	0.6 Ml, Qd		Not Reported
	Paracetamol			S		4 G, Qd		Not Reported
	Paracetamol			S				Not Reported
	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17669289	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010048		32 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Maternal Exposure During Pregnancy; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Certolizumab Pegol			S	Subcutaneous	400 Mg, (Cyclical)		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Q.O.Wk.		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q.O.Wk.		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk, Q.Wk.		Not Reported

	Methotrexate		S	Subcutaneous	Unk	Not Reported
	Sulfasalazine		S	Unknown	Unk	Not Reported
	Prednisone		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	12764963	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076342		61 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	1 Dosage Form		Not Reported
	Naproxen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			S	Unknown	12.5 Milligram		Not Reported
	Xeljanz			S	Oral	50 Milligram, 2 Every 1 Day		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Aleve			S	Unknown			Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Prednisone Teva			S	Unknown	Unk		Not Reported

	Tocilizumab	S	Unknown	Unk	Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Naproxen Sodium	S	Oral	Unk	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	400 Milligram	Not Reported
	Folic Acid	C	Subcutaneous	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
	Insulin	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	2 Dosage Form, Bid	Not Reported
	Celebrex	C	Unknown	2 Dosage Form, Qd	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	13006742	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP015239		53 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug	Alendronate			S	Unknown	70 Mg, Q.Wk.		Apotex
	Alendronate			S				Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex

Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Apo-Leflunomide	S	Oral	Unk	Apotex
	Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Leflunomide	S	Unknown	20 Mg, Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Leflunomide	S	Oral	20 Mg, Unk	Apotex
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, B.I.Wk.	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	25 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	25 Mg, Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	25 Mg, Q.O.Wk.	Not Reported
	Enbrel	S	Unknown	25 Mg, B.I.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk, Cyclical	Not Reported
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Week	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12.5 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported

Orencia	S	Unknown	760 Mg, Q.Wk.	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk (Therapy Duration 365 Unspecified Unit)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Unknown	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	S	Unknown	360 Mg, Q.M.T.	Not Reported
Tocilizumab	S	Unknown	680 Mg, Q.M.T.	Not Reported
Tocilizumab	S	Unknown	360 Mg, Q.M.T.	Not Reported
Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Weeks	Not Reported
Actemra	S	Unknown	360 Mg, Q.M.T.	Not Reported
Actemra	S	Unknown	680 Mg, Q.M.T.	Not Reported
Actemra	S	Unknown	2.68 Mg, 1 Every 4 Weeks	Not Reported
Actemra	S	Unknown	2.68 Mg, 1 Every 4 Weeks	Not Reported
Actemra	S	Unknown	680 Mg, Q.M.T.	Not Reported
Methotrexate	S	Oral	10 Mg, Q.Wk.	Not Reported
Methotrexate	S	Oral	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Oral	10 Mg, 1 Every 4 Weeks	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituximab	S	Unknown	1000 Mg, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Qd	Not Reported
Sulfasalazin	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazin	S	Unknown	Unk	Not Reported

Myochrysine	S	Parenteral	50 Mg, Q.M.T.	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Q.M.T.	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Q.Wk.	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	17.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	12 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	70 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	12 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	15.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	15 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	10 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	10 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Unknown	15 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Unknown	12.5 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Unknown	12 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	12 Mg, Unk	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Q.Wk.	Not Reported
Arava	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

	Simponi	S	Unknown	360 Mg, Q.M.T.	Not Reported
	Simponi	S	Subcutaneous	680 Mg, Q.M.T.	Not Reported
	Etanercept	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Etanercept	S	Unknown	25 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)	500 Mg, Unk	Not Reported
	Ciclosporin	C	Unknown	150 Mg, Qd	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
	Alendronate Sodium	C	Unknown	70 Mg, Q.Wk.	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Prednisolone	C	Unknown	10 Mg, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	14267213	EXPEDITED (15-DAY)		OT	CA-ROCHE-2032902		71 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Off Label Use; Pain; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatic Disorder; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Plaquenil [Hydroxychloroquine Sulfate]		S	Oral	Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Not Reported
	Simponi		S	Subcutaneous	Not Reported
	Sulfasalazine		S	Unknown	Not Reported
	Humira		S	Subcutaneous	Not Reported
	Hydroxychloroquine		S	Unknown	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown	Not Reported
	Methotrexate		S	Intra-arterial	Not Reported
	Cimzia		S	Subcutaneous	Not Reported
	Leflunomide		S	Unknown	Not Reported
	Sodium Aurothiomalate		S	Parenteral	Not Reported
	Gold		S	Unknown	Not Reported
	Piroxicam		C		Not Reported
	Prednisone		C	Unknown	Not Reported
	Morphine		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	14921412	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-044420		63 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	2.0 Dosage Form, Qd		Not Reported
	Hydroxychloroquine			S	Oral	10.0 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	5.0 Milligram, Bid		Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Endocervical	Unk	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Cyclosporine	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	20 Milligram	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
Methotrexate	S	Oral	20 Milligram	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Ciclosporin	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Oral	2 Dosage Form, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Oral	10 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Methotrexate Sodium	S	Oral	20 Milligram	Not Reported

	Xeljanz	C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz	C	Unknown	2 Ot, Qd		Not Reported
	Xeljanz	C	Oral	10 Milligram, Qd		Not Reported
	Xeljanz	C	Oral	5 Milligram, Qd		Not Reported
	Xeljanz Xr	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	15208961	EXPEDITED (15-DAY)		HO, OT	GR-ALLERGAN-1835963US			Male	GRC

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Leukopenia; Microangiopathic Haemolytic Anaemia; Orthopnoea; Raynaud'S Phenomenon; Renal Impairment; Scleroderma; Scleroderma Renal Crisis; Thrombocytopenia; Weight Decreased	Citalopram Hydrobromide Unk			S	Unknown	Unk		Allergan
	Alprazolam			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Q Week		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisolone			S	Unknown	7.5 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Folate			S	Unknown	5 Mg, Q Week		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Etanercept			S				Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Captopril			S	Unknown	Unk		Not Reported
	Captopril			S				Not Reported
	Valsartan			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	15389857	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-082887		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blister; Confusional State;	Abatacept			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb

Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Abatacept	S	Unknown	Unk	Bristol Myers Squibb
	Acetaminophen	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Milligram, Q4wk, 84 Days	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Milligram, Q4wk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Milligram 4 Every 1 Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Milligram 4 Every 1 Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	752.8 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	728 Milligram	Not Reported
	Chlorhexidine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Oxycodone Hydrochloride	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Oxycodone Terephthalate	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Periarticular	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Unk	Not Reported
	Chlorhexidine Gluconate	S	Unknown	Unk	Not Reported
	Sulfamethoxazole	S	Unknown	Unk	Not Reported
	Oxycodone And Acetaminophen	S	Unknown	Unk	Not Reported

Oxycodone	S	Unknown	Unk	Not Reported
Oxycodone Actavis	S	Unknown	Unk	Not Reported
Periogard	S	Buccal	Unk	Not Reported
Apo Acetaminophen	S	Unknown	Unk	Not Reported
Arava	C	Oral	20 Milligram, Qd	Not Reported
Arava	C	Unknown	Unk	Not Reported
Desogestrel And Ethinyl Estradiol	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Pantoprazole Sodium	C	Unknown		Not Reported
Hydroxychloroquine Phosphate	C	Unknown	Unk	Not Reported
Prednisone	C	Oral	7.5 Milligram	Not Reported
Cetirizine Hydrochloride	C	Unknown	Unk	Not Reported
Paracetamol	C	Unknown	Unk	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Milligram, Qd	Not Reported
Tylenol With Codeine	C	Unknown	Unk	Not Reported
Paracetamol Codeine	C	Unknown	Unk	Not Reported
Cetrizine	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	16743894	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-056074			Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In	Pregabalin 100 Mg Capsules, Hard			S	Unknown	1 Dosage Form, 3 Times A Day (1-1-1)		Not Reported
	Ramipril 2.5mg			S	Oral	1 Dosage Form, Two		Aurobindo

Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment				Times A Day	
	Sildenafil	S	Unknown	60 Milligram, Once A Day, Daily Dose	Aurobindo
	Eliquis	S	Unknown	1 Dosage Form, Two Times A Day (1-0-1)	Not Reported
	Eliquis	S	Unknown	2.5 Milligram, Two Times A Day	Not Reported
	Omeprazole	S	Oral	1 Dosage Form, Two Times A Day	Not Reported
	Quensyl	S	Unknown	40 Milligram, Once A Day, 1 Dosage Form, Two Times A Day (1-0-1)	Not Reported
	Quensyl	S	Unknown	2 Dosage Form, Once A Day (1 Df, Bid)	Not Reported
	Roactemra	S	Subcutaneous	162 Milligram, Every Week	Not Reported
	Roactemra	S	Subcutaneous	162 Milligram, Every Week	Not Reported
	Spasmolyt	S	Unknown	1 Dosage Form, Once A Day (15, Qd ((1-0-0))	Not Reported
	Spasmolyt	S	Unknown	30 Milligram, Once A Day	Not Reported
	Tocilizumab	S	Subcutaneous	162 Milligram, Every Week	Not Reported
	Volibris	S	Unknown	30 Milligram, Once A Day	Not Reported
	Volibris	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Volibris	S	Unknown	1 Dosage Form, Once A Day	Not Reported
	Lyrica	S	Unknown	100 Milligram, 3 Times A Day	Not Reported
	Eliquis	C	Unknown	5 Milligram, Once A Day (2.5 Mg, Bid)	Not Reported
	Omeprazole	C	Unknown	40 Milligram, Once A Day (20 Milligram, Bid)	Not Reported
	Quensyl	C	Unknown	40 Milligram, Once A Day (20 Mg Bid)	Not Reported

Ramipril	C	Unknown	5 Milligram, Once A Day (2.5 Mg, Bid)		Not Reported
Spasmolyt	C	Unknown	15 Milligram, Once A Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17004240	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-103496		37 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Aleve			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Simponi			C	Subcutaneous	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17040026	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3002083-00		43 YR	Female	CAN

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

Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Humira	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Solution Use Single-Use Pre-Filled Syringe	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Arava	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported

Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Plaquenil	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral		Not Reported
Topicort [Hydrocortisone Acetate]	S	Topical		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tofacitinib Citrate	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Cetirizine	S	Unknown		Not Reported
Alendronate Sodium	S	Oral		Not Reported
Diclofenac	S	Unknown		Not Reported
Desoximetasone	S	Oral		Not Reported
Arava	S	Intravenous (not otherwise specified)	Powder For Solution For Infusion	Not Reported
Etanercept	S	Subcutaneous		Not Reported
Paracetamol	S	Unknown		Not Reported
Sarilumab	S	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Atasol	C			Not Reported
Salazopyrin	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17184962	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-		43 YR	Female	CAN

CA2019230308

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride			S	Unknown	10 Mg		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	20 Mg		Glaxosmithkline
	Paracetamol			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	25 Mg		Glaxosmithkline
	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	5 Mg		Glaxosmithkline
	Folic Acid			S	Oral	5 Mg		Glaxosmithkline
	Folic Acid			S	Oral	1 Mg		Glaxosmithkline
	Folic Acid			S	Unknown	1 Mg		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Desoximetasone			S	Unknown	Unk		Glaxosmithkline
	Cortisone Acetate			S	Oral	Unk		Glaxosmithkline
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Stelara			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported

Hydroxychloroquine Sulfate	S	Subcutaneous	400 Mg, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	40 Mg, Qd	Not Reported
Apo Prednison	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Mg	Not Reported
Arava	S	Oral	Unk	Not Reported
Cortison (Cortisone)	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Topical	25 Mg	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, We	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	4 Mg, Solution For Injection	Not Reported
Hydroxychloroquine	S	Oral	400 Mg, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Leflunomide Sandoz	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Qd	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Intra-arterial	25 Mg	Not Reported
Methotrexate	S	Oral	25 Mg	Not Reported
Methotrexate Sodium	S	Oral	25 Mg	Not Reported
Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil (Hydroxychloroquine	S	Oral	40 Mg, Qd	Not Reported

Sulfate)					
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	40 Mg, Qd		Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Sarilumab	S	Unknown	Unk		Not Reported
Sulfasalazine	S	Oral	1 G, Qd		Not Reported
Sulfasalazine	S	Oral	500 Mg		Not Reported
Sulfasalazine	S	Oral	1 G, Qd		Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Unk		Not Reported
Topicort (Hydrocortisone Acetate)	S	Unknown	Unk		Not Reported
Topicort (Hydrocortisone Acetate)	S	Oral	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported
Xeljanz	S	Unknown	Unk		Not Reported
Atasol (Paracetamol)	C	Unknown	Unk		Not Reported
Salazopyrin	C	Unknown	Unk		Not Reported
Tofacitinib Citrate	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17191010	EXPEDITED (15-DAY)		OT	NVSC2019CA076411			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported

Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	1 Mg	Not Reported
	Folic Acid	S	Unknown	5 Mg	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg Solution	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Tocilizumab	S	Subcutaneous	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Mg	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

Sulfasalazine	S	Subcutaneous	500 Mg		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17350586	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004765			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Milligram		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17554482	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022709		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased;	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	250 Milligram		Bristol Myers Squibb
	Orencia			S	Intravenous (not	200 Milligram, Qmo		Bristol Myers Squibb

Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting	Actemra	S	otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
	Adalimumab	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Anakinra	S	Unknown	50 Milligram	Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	50 Milligram	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram	Not Reported
	Enbrel	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram	Not Reported
	Infliximab	S	Intravenous (not	3 Milligram/Kilogram,	Not Reported

		otherwise specified)	Q6wk	
Infliximab	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Q2wk	Not Reported
Methotrexate	S	Subcutaneous	Unk Unk, Qwk	Not Reported
Methotrexate	S	Unknown	15 Milligram/Sq. Meter, Qwk	Not Reported
Methotrexate	S	Unknown	15 Milligram/Sq. Meter, Q2wk	Not Reported
Naproxen	S	Unknown		Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	50 Milligram, Bid	Not Reported
Prednisone	S	Unknown	50 Milligram	Not Reported
Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
Prednisone	S	Oral	3 Milligram, Bid	Not Reported
Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
Tocilizumab	S	Unknown		Not Reported
Triamcinolone Acetonide	S	Intra-articular		Not Reported
Triamcinolone Acetonide	S	Unknown		Not Reported
Triamcinolone Hexacetonide	S	Other		Not Reported
Triamcinolone Hexacetonide	S	Unknown		Not Reported
Triamcinolone	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Qd	Not Reported
Folic Acid	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17566294	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200321035			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Imuran /00001501/			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17566419	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318563		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Contraindicated Product Administered; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Irritable	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Infliximab, Recombinant			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

Bowel Syndrome; Off Label Use; Rheumatoid Arthritis	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Bimatoprost	C	Ophthalmic	Not Reported
	Nexium /01479302/	C	Unknown	Not Reported
	Suphedrine /00005601/	C	Unknown	Not Reported
	Trazodone	C	Unknown	Not Reported
	Tylenol /00020001/	C	Unknown	Not Reported
	Tylenol /00020001/	C		Not Reported
	Valsartan	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Esomeprazole Sodium	C	Unknown	Not Reported
	Lumigan Rc	C	Ophthalmic	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17605662	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332777		65 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Blood Pressure Increased; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Glumetza	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Lyrica	S	Oral	Not Reported
	Lyrica	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Arava	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Acetaminophen	C		Not Reported
	Altace	C	Unknown	Not Reported
	Asa	C		Not Reported
	Codeine	C		Not Reported
	D-Alpha Tocopherol	C		Not Reported
	Ergocalciferol	C		Not Reported
	Folic Acid	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17606950	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318841		75 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Red Blood Cell Sedimentation Rate Increased; Urticaria	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Subcutaneous			Janssen
	Remicade			S	Unknown			Janssen
	Infliximab, Recombinant			S	Unknown			Janssen
	Infliximab, Recombinant			S	Unknown			Janssen
	Adalimumab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Minocycline			C	Unknown			Not Reported

	Penicillamine	C	Unknown	Not Reported
	Prednisolone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tocilizumab	C	Unknown	Not Reported
	Actemra	C	Unknown	Not Reported
	Phenylbutazone	C	Unknown	Not Reported
	Tofacitinib	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17640700	EXPEDITED (15-DAY)		LT, OT	FR-SA-2020SA087400		18 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Hepatocellular Injury; Infection; Inflammation; Pyrexia; Respiratory Disorder	Hydroxychloroquine Sulfate			S	Other	1200 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Other	400 Mg, Qd		Sanofi
	Lovenox			S	Subcutaneous	0.6 Ml, Qd		Sanofi
	Midazolam			S	Intravenous (not otherwise specified)	5 Mg/Ml, Qd		Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)	40 Mg, Qd		Not Reported
	Loxen [Loxoprofen Sodium]			S	Intravenous (not otherwise specified)	30 Mg, Qd		Not Reported
	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch			S	Other	2 Df Bag		Not Reported
	Paracetamol			C	Other	4 G, Qd		Not Reported
	Paracetamol			C				Not Reported
	Lasilix [Furosemide]			C	Other	30 Mg, Qd		Not Reported
	Novorapid			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Doliprane			C				Not Reported

	Doliprane	C				Not Reported
	Diffu K	C	Other	3.6 G, Qd		Not Reported
	Diffu K	C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17655387	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3357377-00		76 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Ventricular Tachycardia	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17656097	EXPEDITED (15-DAY)		LT, OT	FR-SA-2020SA080271		71 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alkalosis; Alkalosis; Deep Vein Thrombosis; Haematuria; Haemoglobin Decreased; Hyperglycaemia; Overdose; Oxygen Saturation Decreased; Quadriparesis; Vascular Device Infection	Hydroxychloroquine Sulfate			S	Other	600 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Other	400 Mg, Qd		Sanofi
	Lovenox			S	Subcutaneous	0.6 Ml, Qd		Sanofi
	Lovenox			S	Subcutaneous	0.7 Ml, Qd		Sanofi
	Paracetamol			S	Other	4 G, Qd		Not Reported
	Paracetamol			S				Not Reported
	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch			C	Other	2 Df, Qd		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Lasilix [Furosemide]			C	Parenteral	40 Mg, Qd		Not Reported
	Lantus			C	Subcutaneous	20 Iu, Qd		Not Reported
	Pantoprazole			C	Oral	40 Mg, Qd		Not Reported
	Pantoprazole			C				Not Reported
	Pantoprazole			C				Not Reported
	Tienam			C	Intravenous (not	1 G, Q8h		Not Reported

otherwise specified)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17666050	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3361715-00		80 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17667413	EXPEDITED (15-DAY)		LT, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000290			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypokalaemia; Ventricular Tachycardia	Furosemide			S	Intravenous (not otherwise specified)	2 Df, Qd		Validus
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	Unk		Not Reported
	Sufentanil			C		Unk		Not Reported
	Perfalgan			C		Unk		Not Reported
	Noradrenalin /00127501/			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Tazocilline			C		Unk		Not Reported
	Transipeg /00754501/			C		Unk		Not Reported
	Potassium Chloride			C		Unk		Not Reported
	Nimbex /01302502/			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17671057	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009843			Female	CAN

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

Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Apotex
	Hydroxychloroquine	S	Unknown	200 Mg, B.I.Wk.	Apotex
	Hydroxychloroquine	S	Unknown	200 Mg, Unk (Cyclical)	Apotex
	Hydroxychloroquine	S	Unknown	400 Mg, Unk Cyclical	Apotex
	Hydroxychloroquine	S	Unknown	400 Mg, T.I.W	Apotex
	Hydroxychloroquine	S	Unknown	200 Mg, Q.O.Wk.	Apotex
	Apo-Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S	Unknown	Unk	Apotex
	Methotrexate	S	Subcutaneous	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Actemra	S	Subcutaneous	162 Mg, B.I.Wk.	Not Reported
	Actemra	S	Subcutaneous	162 Mg, Q.O.Wk.	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Prednisone	C	Unknown	20 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	11433670	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-056507			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Product Use	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Not Reported

Issue; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, Qd	Not Reported
	Apo Hydroxyquine	S	Oral	400 Milligram	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Arava	S	Oral	10 Milligram, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk, Qmo	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk, Qd	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Apo-Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
	Naprosyn [Naproxen]	S	Unknown	Unk Prn	Not Reported
	Methotrexate	S	Intramuscular	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Naproxen	S	Unknown	Unk Unk, Prn	Not Reported
	Ramipril	C	Unknown	Unk	Not Reported
	Cardio Aspirin	C	Unknown	81 Milligram	Not Reported
	Metformin	C	Unknown	Unk	Not Reported
	Lantus	C	Subcutaneous	Unk	Not Reported
	Insulin [Insulin Human]	C	Unknown	Unk	Not Reported
	Vitamin D [Ergocalciferol]	C	Unknown	Unk	Not Reported
	Calcium [Calcium Gluconate]	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk Prn	Not Reported
	Lozide [Gliclazide]	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

	Vitamin D Nos		C	Unknown	Unk	Not Reported
	Calcium		C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	11619820	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1477576-00			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Foot Deformity; Foot Deformity; Hand Deformity; Hand Deformity; Hypertension; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Musculoskeletal Disorder; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Cyclical Frequency		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported

Methotrexate	S	Subcutaneous		Not Reported
Risedronate Sodium	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	11878759	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20151223430			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Back Injury; Confusional State; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Hospitalisation; Injury; Muscular Weakness; Nausea; Off Label Use; Product Label Confusion; Treatment Failure; Vomiting	Simponi			S	Subcutaneous			Janssen
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclic(Every 2 Weeks) 40 Mg/0.8 Ml		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Enbrel			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	12913683	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092891		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	25 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Oral	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cortisone			S	Oral	Unk, Prn		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Oral	5 Milligram		Not Reported
	Folic Acid			S	Oral	1 Milligram		Not Reported
	Folic Acid			S	Unknown	1 Dosage Form		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported

Folic Acid	S	Unknown	500 Milligram	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	5 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not	Unk	Not Reported

		otherwise specified)		
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
Sulfathalidine	S	Subcutaneous	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
Apo Folic	S	Unknown	5 Milligram	Not Reported
Apo Prednison	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
Methotrexate	S	Unknown	Unk, Qd	Not Reported
Methotrexate	S	Oral	Unk, Qd	Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram, Qwk	Not Reported
Cortisone Acetate	S	Oral	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	10 Milligram	Not Reported
Cortisone	S	Topical	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13109301	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-065623		12 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adrenal Insufficiency; Antibody Test Positive;	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb

Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased;	Orencia	S	Unknown		Bristol Myers Squibb
	Triamcinolone Acetonide	S	Intra-articular	Unk	Bristol Myers Squibb
	Triamcinolone Acetonide	S	Unknown		Bristol Myers Squibb
	Triamcinolone Acetonide	S	Unknown		Bristol Myers Squibb
	Triamcinolone Acetonide	S	Unknown		Bristol Myers Squibb
	Triamcinolone Acetonide	S	Oral	5 Milligram, Qd	Bristol Myers Squibb
	Triamcinolone Acetonide	S	Unknown		Bristol Myers Squibb
	Triamcinolone Acetonide	S	Unknown		Bristol Myers Squibb
	Triamcinolone Acetonide	S	Unknown		Bristol Myers Squibb
	Enbrel	S	Subcutaneous	12.5 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
	Enbrel	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Infliximab	S	Unknown	5 Milligram	Not Reported
	Infliximab	S	Unknown	3 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown		Not Reported
	Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 2 Every 1 Week	Not Reported

Therapy Non-Responder; Vomiting; Wheelchair User	Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Milligram	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Apo Triamcinolone Aq	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Adalimumab	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Anakinra	S	Unknown	50 Milligram, Qwk	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Triamcinolone	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	70.0 Gram	Not Reported

	Gamastan	S	Intramuscular	70 Gram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Dosage Form	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Naproxen Sodium	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	25 Milligram(2 Every 1 Week)	Not Reported
	Etanercept	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13519755	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038176		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Paracetamol			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Enbrel	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	500 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Folic Acid	S	Oral	1 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Oral	5 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	4 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Oral	Unk, Qd	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	1 Mg, Unk	Not Reported
	Prednisone	S	Unknown	40 Milligram	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Oral	10 Milligram	Not Reported

Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	20 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 G, Qd	Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Sulfasalazine	S	Unknown	1 G, Bid	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	40 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Qd	Not Reported
Apo-Prednisone	S	Unknown	5 Mg, Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Desoximetasone	S	Unknown	25 Milligram	Not Reported
Desoximetasone	S	Cutaneous	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported

Xeljanz	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Hydroxychloroquine Phosphate	S	Oral	400 Milligram, Qd	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Apo-Folic Acid	S	Unknown	15 Milligram	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	25 Milligram	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	50 Milligram	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Hydrocortisone Acetate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Subcutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Other	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	40 Milligram, Qd	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Oral	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown		Not Reported
Leflunomide	C	Oral	Unk	Not Reported
Lisinopril	C	Unknown		Not Reported
Prednisolone	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown		Not Reported
Diclofenac	C	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	13854282	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070658			Female	CAN

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

Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Orencia	S	Unknown	125 Milligram, Qwk	Bristol Myers Squibb
	Enbrel	S	Subcutaneous	Unk Unk, Qwk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Q2wk	Not Reported
	Enbrel	S	Subcutaneous	1 Dosage Form	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown	Unk, Q2wk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Advil [Mefenamic Acid]	C	Unknown		Not Reported
	Prednisone	C	Oral	6 Milligram, Qd	Not Reported
	Prednisone	C	Oral	10 Milligram, Qd	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Dequalinium Chloride	C	Unknown	Unk	Not Reported
	Mefenamic Acid	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Advil [Ibuprofen]	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	14778860	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009970		52 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Apo-Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Subcutaneous	400 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	15843027	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20190118848		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ankle Arthroplasty; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Foot Deformity; Foot Operation; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Plaquenil	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Gold	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Risedronate Sodium	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	C	Unknown	Not Reported
Risedronate	C	Unknown	Not Reported
Xeljanz	C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16001840	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1017013		78 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain Upper; Abnormal Loss Of Weight; Adverse Drug Reaction; Adverse Reaction; Arthralgia; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Eating Disorder; Feeding Disorder; Foot Operation; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain;	Diclofenac Potassium			S	Unknown			Actavis
	Diclofenac Potassium			S	Unknown			Actavis
	Diclofenac Potassium			S	Unknown			Actavis
	Diclofenac Potassium			S				Actavis
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Acetylsalicylic Acid			S	Oral			Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Acetylsalicylic Acid			S				Not Reported
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Methotrexate			S				Barr
	Naproxen			S	Unknown			Teva

Headache; Hypophagia;	Naproxen	S		Teva
Mobility Decreased;	Naproxen	S		Teva
Musculoskeletal Disorder;	Naproxen	S		Teva
Nausea; Off Label Use; Pharyngitis; Shoulder Arthroplasty; Vomiting; Weight Decreased	Sulfamethoxazole And Trimethoprim	S	Unknown	Actavis
	Sulfamethoxazole And Trimethoprim	S		Actavis
	Sulfamethoxazole And Trimethoprim	S		Actavis
	Sulfamethoxazole And Trimethoprim	S		Actavis
	Ibuprofen	S	Unknown	Actavis
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Arava	S		Not Reported
	Aspirin	S	Oral	Not Reported
	Aspirin	S		Not Reported
	Aspirin	S		Not Reported
	Aspirin	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Enbrel	S		Not Reported
	Enbrel	S		Not Reported
	Gold Injections	S	Unknown	Not Reported
	Gold Injections	S		Not Reported
	Gold Injections	S		Not Reported
	Gold Injections	S		Not Reported
	Humira (Adalimumab)	S	Subcutaneous	Not Reported
	Humira (Adalimumab)	S		Not Reported
	Humira (Adalimumab)	S		Not Reported
	Humira (Adalimumab)	S		Not Reported
	Hydroxychloroquine Sulfate Tablets	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate Tablets	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate Tablets	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported

Tablets			
Motrin	S	Unknown	Not Reported
Motrin	S		Not Reported
Motrin	S		Not Reported
Motrin	S		Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S		Not Reported
Plaquenil	S		Not Reported
Plaquenil	S		Not Reported
Sodium Aurothiomalate Injection Bp	S	Parenteral	Not Reported
Sodium Aurothiomalate Injection Bp	S	Unknown	Not Reported
Sodium Aurothiomalate Injection Bp	S		Not Reported
Sodium Aurothiomalate Injection Bp	S		Not Reported
Vitamin C	S	Unknown	Not Reported
Vitamin C	S		Not Reported
Vitamin C	S		Not Reported
Vitamin C	S		Not Reported
Tramadol Hydrochloride	S	Unknown	Not Reported
Naprosyn	S	Unknown	Not Reported
Naprosyn	S		Not Reported
Naprosyn	S		Not Reported
Naprosyn	S		Not Reported
Voltaren	S	Unknown	Not Reported
Acetylsalicylic Acid/Clopidogrel	S	Unknown	Not Reported
Apo-Diclofenac	S	Unknown	Not Reported
Apo-Sulfatrim	S	Unknown	Not Reported
Tramadol Hydrochloride	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16047193	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020789		39 YR	Female	CAN

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

Condition Aggravated; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Methotrexate	S	Oral			Barr
	Methotrexate	S	Subcutaneous			Barr
	Leflunomide	S	Unknown			Barr
	Celebrex	S	Oral	200milligram		Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Unknown			Not Reported
	Humira	S	Subcutaneous			Not Reported
	Plaquenil	S	Unknown			Not Reported
	Rituxan	S	Unknown			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Actemra	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/	C	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/	C	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16397631	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-210010			Unknown	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphonia; Infection Reactivation; Leishmaniasis; Sensation Of Foreign Body; Visceral Leishmaniasis; Visceral Leishmaniasis	Diclofenac			S	Unknown	Unk ()		Sun
	Hydroxychloroquine			S	Unknown	Unk ()		Sun
	Lansoprazole			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk ()		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	16576751	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-034879		66 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; Abdominal Pain Upper; Acne; Appendicitis Perforated; Arthralgia; Asthenia; Bradycardia; Depressed Mood; Erythema; Fatigue; Gastrointestinal Disorder; Headache; Hypertension; Lethargy; Malaise; Nausea; Pain; Pain In Extremity; Peritonitis; Rash; Synovial Cyst	Abatacept			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb
	Abatacept			S	Unknown			Bristol Myers Squibb
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Cipralex [Escitalopram]			C	Unknown	Unk		Not Reported
	Estradiol			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Colace			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17165875	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151435			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bone Erosion; Drug Ineffective; Pneumocystis Jirovecii Pneumonia; Pulmonary Fibrosis; Synovitis	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown	400 Milligram Daily;		Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17188130	EXPEDITED (15-DAY)		OT	JP-ADVANZ PHARMA-GSH201901-000131			Unknown	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Photopsia; Retinal Dystrophy	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Cellcept			C		Unk		Not Reported
	Arotinolol Hydrochloride			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Takecab			C		Unk		Not Reported
	Rivotril			C		Unk		Not Reported
	Bonoteo			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17215818	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1952857US			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid	Actonel			S	Unknown	35 Mg, Q Week		Allergan
	Actonel			S	Unknown	35 Mg, Q Week		Allergan
	Actonel			S	Unknown	35 Mg, Q Week		Allergan
	Actemra			S	Subcutaneous	Unk Mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Anakinra			S	Subcutaneous	100 Mg		Not Reported
	Anakinra			S	Subcutaneous	100 Mg		Not Reported
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2weeks		Not Reported

Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine	S	Unknown	300 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Oral	20 Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Mg	Not Reported
	Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown	300 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17365297	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005932			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported

Fosamax	S	Oral	Unk		Not Reported
Fosamax	S	Unknown	Unk		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Hydroxychloroquine	S	Unknown			Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk		Not Reported
Diclofenac Sodium	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17425099	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2020023487		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Anaemia; Dizziness; Haemolytic Uraemic Syndrome; Hypotension; Nausea; Product Dose Omission; Renal Injury; Urinary Tract Infection	Benlysta			S	Intravenous (not otherwise specified)	Unk Unk, We		Glaxosmithkline
	Cipro			S	Unknown	Unk		Glaxosmithkline
	Plaquenil			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17543214	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-020534			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Oral	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

Methotrexate	S	Oral	Unk		Not Reported
Methotrexate	S	Unknown	Unk		Not Reported
Methotrexate	S	Intra-arterial	25 Milligram		Not Reported
Methotrexate Sodium	S	Unknown	Unk		Not Reported
Phthalylsulfathiazole	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk		Not Reported
Tocilizumab	S	Unknown			Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Prednisone	S	Oral	Unk		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Sulfasalazine	S	Unknown	500 Milligram		Not Reported
Hydroxychloroquine Sulfate	S	Oral			Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17605652	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332789		50 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use;	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration 2.0 Years		Janssen
	Actemra			S	Unknown			Not Reported

Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava	S	Oral		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Certolizumab Pegol	S	Unknown		Not Reported
	Ciclosporin	S	Vaginal		Not Reported
	Ciclosporin	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Pregabalin	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Lyrica	S	Vaginal		Not Reported
	Piroxicam	C			Not Reported
	Prednisone	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17623406	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342133			Female	CAN

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

Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Simponi		S	Subcutaneous		Janssen
	Cimzia		S	Subcutaneous	Single Use	Not Reported
	Cimzia		S	Subcutaneous		Not Reported
	Enbrel		S	Unknown	5 Years	Not Reported
	Enbrel		S	Unknown		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Humira		S	Subcutaneous		Not Reported
	Leflunomide		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Methotrexate		S	Unknown		Not Reported
	Sulfasalazine		S	Unknown	7 Months	Not Reported
	Hydroxychloroquine Sulfate		S	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported
	Xeljanz		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17623534	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340450		56 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Alopecia; Arthropathy; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Prescribed Overdose; Rheumatoid Arthritis; Synovitis; Systemic Lupus	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

Erythematosus; Underdose; Vomiting	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Naprosyn /00256201/	C	Unknown	Not Reported
	Naprosyn /00256201/	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17641316	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029045			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Arthropathy; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Fosamax			S	Oral	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported

Humira	S	Subcutaneous			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Methotrexate	S	Unknown			Not Reported
Phthalylsulfathiazole	S	Unknown			Not Reported
Prednisone	S	Unknown			Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17662286	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-ADVANZ PHARMA-202003002885			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; General Physical Health Deterioration; Off Label Use; Pneumonia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk (Film Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17666360	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009894		35 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use;	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported

Product Use Issue; Rash; Rheumatoid Arthritis	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	20 Mg, Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	300 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5.0 Mg, Bid	Not Reported
	Magnesium	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	400 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17667419	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200409451		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blister; Confusional State; Contraindicated Product Administered; Contusion; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Chloraprep			S		Topical		Not Reported
	Chlorhexidine Gluconate			S	Unknown	Oral Rinse		Not Reported

Increased; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pregnancy; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycodone	S			Not Reported
	Oxycodone Hydrochloride	S			Not Reported
	Oxycodone Terephthalate	S			Not Reported
	Oxycodone And Acetaminophen	S	Unknown		Not Reported
	Periogard	S	Buccal	Alcohol Free	Not Reported
	Sulfamethoxazole	S			Not Reported
	Sulfamethoxazole And Trimethoprim	S			Not Reported
	Arava	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Cetirizine	S	Unknown		Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Plaquenil /00072602/	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Cortisone	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported

Methotrexate	S	Oral	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Oral	Not Reported
Sulfathalidine	S	Oral	Not Reported
Tofacitinib	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Topicort /00028604/	S	Cutaneous	Not Reported
Chlorhexidine	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Cetirizine Hydrochloride	C		Not Reported
Desogestrel And Ethinylestradiol	C		Not Reported
Ibuprofen	C		Not Reported
Pantoloc /01263201/	C		Not Reported
Pantoprazole Sodium	C		Not Reported
Paracetamol/Codeine	C		Not Reported
Reactine /00884302/	C		Not Reported
Tylenol /00020001/	C		Not Reported
Tylenol With Codeine	C		Not Reported
Atasol /00020001/	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17672254	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200411531			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Psoriatic Arthropathy	Simponi			S	Subcutaneous			Janssen
	Stelara			S	Subcutaneous			Janssen

	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Cimzia	S	Subcutaneous	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Otezla	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Apr-2020	17574299	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201806-002062			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Off Label Use; Retinal Toxicity; Toxicity To Various Agents	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	7.01 Mg/Kg, Qd (Total Cumulative Dose 402 G)		Concordia
	Cyclophosphamide			S	Unknown	21-Day Cycles		Not Reported
	Docetaxel			S	Unknown	21-Day Cycles		Not Reported
	Anastrozole			S	Unknown	Unk		Not Reported